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The Correlation Between Neuropathy Limitations and Depression in Chemotherapy Patients

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The Correlation Between Neuropathy Limitations and Depression
in Chemotherapy Patients

By

Melissa Thebeau

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science
College of Nursing
University of South Florida

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The Correlation Between Neuropathy Limitations and Depression in Chemotherapy Patients

Melissa Thebeau

ABSTRACT

This study examined the association between neuropathy limitations and depression in chemotherapy patients currently on treatment with a taxane-based, platinum-based or plant alkaloid chemotherapy drug.

The Overall Neuropathy Limitations Scale (ONLS) and the Beck Depression Inventory-Short Form (BDI-SF) were used to assess neuropathy limitations and depression in 24 chemotherapy patients with reported symptoms of peripheral neuropathy. Average age of patients was 65 years, 66.6% were female, and average number of chemotherapy cycles completed was 5.6. Of the 24 patients, 37.5% of patients were on a single agent taxane-based drug, 37.5% of patients were on a taxane-based drug with a platinum based drug, 16.6% of patients were on a plant alkaloid, and 8.3% were on a combination of a taxane-based and another non-neurotoxic chemotherapy drug.

The scores on both the BDI-SF and ONLS were very low. The mean score on the BDI-SF was 4.1 with a standard deviation of 2.7. The mean score on the ONLS was 2.2 with a standard deviation of 1.5. The study showed a non-significant relationship between neuropathy limitations and depression in chemotherapy patients.

These findings show no association between neuropathy limitations and depression. Although all of these patients had symptoms of peripheral neuropathy, they were not severe enough to interfere with daily activities. The lack of relationship was not

unexpected given the low scores on both the BDI-SF and ONLS. Future research should re-evaluate this relationship with a larger, more diverse sample.

Chapter One Introduction

Cancer accounts for nearly a quarter of deaths in the United States each year, only outranked by heart disease. In 2009, there were an estimated 1,479,350 new cancer cases diagnosed (American Cancer Society, 2010). Of these patients, nearly half of them will receive chemotherapy treatment. Scientists have made a great deal of progress in developing treatments to manage the potential side effects of chemotherapy. Common chemotherapy side effects include infections, nausea and vomiting, hair loss, constipation, diarrhea, fatigue, and nerve damage. Of particular concern, these side effects may lead to problems of adherence to treatment and diminished quality of life (Gralla, Houlihan, & Messner, 2010).

One of the side effects of chemotherapy, nervous system damage, can present with a unique set of complications. Peripheral neuropathy (PN) is a complication that patients experience when the chemotherapy drugs damage their nerves. It is often characterized by pain, numbness, and tingling in the hands and feet (Gralla, Houlihan, & Messner, 2010). Types of chemotherapy treatments that commonly cause PN include: taxanes like paclitaxel, docetaxel and abraxane; platinum drugs such as cisplatin and oxaliplatin; and plant alkaloids such as vincristine, vinorelbine and vinblastine (American Cancer Society, 2010). PN may present as pain, numbness and tingling in the extremities. Ototoxicity, changes in vision, blood pressure, and gastrointestinal function

infrequently occur (Bakitas, 2007). These conditions may cause limitations in a patient's daily activities.

Although effective chemotherapy treatments have been discovered, PN continues to be a common complication affecting nerves including the sensory, motor, and autonomic systems (Stitham, 2008). The limitations that PN cause have the potential to add an increased level of stress and possible anxiety to cancer patients who already are managing many new issues. Individuals who are experiencing PN may be unable to perform many tasks independently, and may be at a higher risk for depression.

There are several factors that put a cancer patient at risk for depression. Some of these risk factors include living with the disease, medications that are prescribed to manage the cancer and side effects, poor support systems, and unrelieved symptoms such as pain (Hamilton, 2005). A paucity of research has been conducted to determine the effect of peripheral neuropathy symptoms on the mental health of those diagnosed with cancer.

Problem Statement

Currently, there is little or no research focusing on the relationship between limitations of chemotherapy induced peripheral neuropathy and depressive symptoms. The purpose of this study was to determine whether there is a relationship between the physical limitations of chemotherapy induced peripheral neuropathy experienced by patients with cancer and depressive symptoms.

This study explored whether patients who are currently under treatment with a taxane-based, platinum-based or plant alkaloid chemotherapy and who are suffering from

limitations of chemotherapy induced peripheral neuropathy have an increased risk of depressive symptoms.

Research Questions

The following questions guided this study:

1. What is the level of depression symptomatology experienced by cancer patients receiving neurotoxic chemotherapy?
2. What is the level of neuropathy limitations in patients receiving neurotoxic chemotherapy?
3. What is the relationship between depressive symptoms and the level of neuropathy limitations in patients receiving neurotoxic chemotherapy?

Definition of Terms

The following terms are defined for purposes of this study:

Peripheral Neuropathy – Occurs when nerves are damaged or destroyed and cannot send messages from the brain and spinal cord to the muscles, skin, and other parts of the body. Symptoms often include: a sensation of wearing an invisible glove or sock, burning sensation or freezing pain, sharp jabbing or electric-like pain, extreme sensitivity to touch, difficulty sleeping because of feet and leg pain, loss of balance and coordination, muscle weakness, difficulty walking or moving the arms, and may include unusual sweating, and abnormalities in blood pressure or pulse. (Miller, 2007)

Neuropathy Limitations – Limitations from neuropathy are caused from damaged nerves in the sensory, motor and autonomic systems. These may cause sensation changes, an inability to determine joint position which causes lack of coordination, loss of dexterity, cramps, falling from legs buckling or tripping over toes. It may cause lack of dexterity,

such as being unable to button a shirt, and lack of muscle control. Heat or cold intolerance, blurred vision, feeling dizzy and/or fainting, and feelings of incomplete bladder emptying. (Stitham, 2008)

Depression – A mood disorder marked by loss of interest or pleasure in living. A feeling of sadness. (Davis, 2001)

Depressive Symptoms – Symptoms of depression may include persistent sadness, hopelessness, loss of energy, irritability, excessive sleep or decreased interest in daily activities. (Davis, 2001)

Significance of the Study

This study investigates a possible relationship between limitations from chemotherapy induced peripheral neuropathy and depression. PN may cause pain and alter patients' activities of daily living. As patients' lose independence with daily activities they may become depressed. Symptoms of PN may limit the ability for an individual to remain independent in activities of daily living. The more severe the symptoms of PN become, the more depressed a person may feel. These feelings of depression may lead to non-adherence with treatment, or diminished quality of life. An analysis of previous studies found that depressed patients are three times less likely to comply with treatments than patients who are not depressed (McManamy, 2009).

Chapter Two Review of Literature

This chapter presents the review of literature relevant to this study. The review of literature describes the symptoms of patients with peripheral neuropathy (PN) and the effect PN has on quality of life. This reviews empiric evidence of the effects of chemotherapy on a patient's emotional status, and having PN and depressive symptoms. Through research, nurses may better understand the relationship between having symptoms of PN and depressive symptoms for patients receiving chemotherapy.

Peripheral Neuropathy and Cancer

Little is known about the development of peripheral neuropathy. Depending on the chemotherapy, PN side effects can range from a sensory and painful neuropathy to a mixed sensory-motor neuropathy with or without autonomic nervous system involvement (Sioka & Kyritsis, 2008). These investigators reviewed the neurotoxicity induced by some of the most common chemotherapeutic agents. The platinum-based drugs were found to cause pure sensory neuropathies, the taxane-based drugs caused a mixed sensory and motor neuropathy, and the plant alkaloids caused both mixed sensory-motor and autonomic neuropathies.

Bakitas (2007) interviewed 28 patients undergoing a variety of different chemotherapy regimens in order to describe the experience and the influence of PN symptoms on everyday life. Patients reported taxane-based chemotherapy induced peripheral neuropathy as one of the most distressing treatment-related symptoms and a

major cause of alterations in function and quality of life. Some participants described the pain as annoying, distracting, and unpleasant. When asked about functional ability, patients rated the discomfort as a three or four out of ten. When asked how much the PN complicated everyday activities, patients rated it as a seven or eight out of ten. PN interrupts dressing, putting on jewelry, balance, and driving (Bakitis, 2007). Emotional distress was attributed to having to deal with physical symptoms of PN, as well as functional and social limitations.

Peripheral Neuropathy and Diabetes

Diabetic peripheral neuropathy (DPN) is a common symptom experienced by those with advanced diabetes. Individuals diagnosed with diabetes are not included in this study; however, those suffering from PN may report similar symptoms. In order to demonstrate the burden of PN, three studies were reviewed.

Argoff, Cole, Fishbain, Irving and Mmed (2006) reviewed the current knowledge about diabetic peripheral neuropathy pain (DPNP). They found that up to 50% of diabetic patients experienced some degree of PN. Nearly a third of those with type 1 diabetes and more than half of those with type 2 diabetes mellitus (DM) had at least one neuropathic symptom. Patients with type 2 DM were more likely to have paresthesia and/or burning pain. The most common presentation of DPNP is pain or tingling in the feet.

Tolle, Xu, and Sadosky (2005) completed a study to determine the burden of DPNP. One-hundred and forty patients with DPNP completed a questionnaire that was focused on pain intensity and impact of functioning. Of the patients who participated, 57% reported moderate pain and 25% reported severe pain. Overall, 91% of the patients

reported using prescription medication for their DPNP. Use of medications for anxiety, depression, or sleep disturbances were reported for nearly half of the patients. This study concluded that DPNP is associated with substantial patient burden resulting from interference with daily functioning.

The final study (Hoffman, Sadosky, & Alvir, 2008) examined functional and health status impairments among patients with DPNP. The study was conducted in 19 countries and included 401 diabetic patients with DPNP. Patients reported DPNP to be more severe at night and stated that it frequently disrupts sleep. The study also showed that PN is associated with major life disturbances including more physician office visits, interference with daily activities such as ambulating and sleeping, and interference at work.

Depression and Cancer

Depression in cancer patients is not yet completely understood. It is not clear whether the depression contributes to the cancer, or whether the stress of having cancer causes the depression. No matter how they happen, cancer and depression seem to coincide. The studies conducted in this area demonstrate that the acceptance of an adjuvant chemotherapy regimen relies heavily on whether or not the patient is depressed (Colleoni, et al., 2000). Patients who undergo initial diagnosis of cancer may become depressed, which can interfere with treatment decisions and adherence to therapy. These patients may have poorer outcomes because symptoms of depression include fatigue, loss of appetite and insomnia. All of these symptoms make it difficult to continue treatment. Results of the study suggested that depression represents a crucial factor for initial acceptance of adjuvant chemotherapy, and that by treating the patient's depression,

practitioners may improve the patients' overall prognosis. One study (Watson et al., 1999) of 395 women with breast cancer revealed that at five years there was a significantly increased risk of death in women with a high score on the depression scale. There was also a correlation for these women between risk of relapse or death in women with high scores on the helplessness and hopelessness scale.

Peripheral Neuropathy and Depression

Pain severity from PN is associated with depression. A study reported in 2005 (Gore et al.) evaluated pain severity, pain-related interference with function, sleep impairment, symptom levels of anxiety and depression, and quality of life among patients with painful DPN. Results were based on patient self-reports. With PN, chronic pain, sleep disturbance, and affective disorders often occur simultaneously and often do not decline over time. The primary pain measure in this study looked at the severity of pain on a 0 to 10 scale, and its interference with seven factors including general activity, mood, walking ability, normal work, relations with others, and enjoyment of life. Results showed that increases in pain resulted in increased difficulty in all seven areas. The Hospital Anxiety and Depression Scale (HADS) measurement tool was used to assess anxiety and depression in the patients. More than half of the patients indicated that they were moderately or severely anxious or depressed.

Summary

The review of literature discusses empiric evidence supporting the relationships between peripheral neuropathy and depression. When patients are depressed, judgment may be impaired. Colleoni et al. (2000) showed that depression is a crucial factor for initial acceptance of treatment. Sioka et al. (2008) demonstrated that the most common

chemotherapy treatments, including taxane-based, platinum-based and plant alkaloid therapies, are all capable of causing neurotoxicity. Symptoms of PN may contribute to depressive symptoms (Bakitas, 2007). This is also confirmed by Tolle et al. (2005), who found that nearly half of patients who were suffering from diabetic peripheral neuropathy were also taking medications for anxiety, depression, or sleep disturbances.

Chapter Three Methods

This chapter presents the study methods. The chapter includes descriptions of the sample, instrumentation, procedures, and data analysis for the study.

Sample

A sample of 30 adult patients receiving chemotherapy treatment with a taxane-based, platinum-based or plant alkaloid therapy was sought. Patients who had reported numbness or tingling in their hands and/or feet were included in the study. Patients who were treated for depression prior to chemotherapy were excluded from the study. Patients with pre-existing PN from diabetes were excluded from the study.

Instrumentation

Beck Depression Inventory-Short Form (BDI-SF)

The Beck Depression Inventory-Short Form (BDI-SF) was developed in 2003 (Appendix A). It assesses the same symptoms as the original Beck Depression Form, with a shorter, less burdensome format for the patients. Rather than the original 21 questions, the BDI-SF presents nine questions with four possible answers each. Total scores range from zero to 36 with scores as follows: 0 to 10 is not depressed, 12 to 19 is depressed and greater than 20 is very depressed (Furlanetto, Mendlowicz, & Bueno, 2005). Individual questions of the BDI-SF assess mood, pessimism, sense of failure, self-dissatisfaction, guilt, punishment, self-dislike, self-accusation, suicidal ideas, crying, irritability, social withdrawal, body image, work difficulties, insomnia, fatigue, appetite,

weight loss, bodily preoccupation, and loss of libido. The BDI-SF was shown to be a valid instrument for the identification of depression, with a sensitivity of 100% and specificity of 83.1% (Furlanetto et al., 2005).

Overall Neuropathy Limitations Scale (ONLS)

The ONLS is a scale that is used to assess limitations and disability caused by peripheral neuropathy (Appendix B). The ONLS is composed of two sections that total 12 questions. Items 1 to 6 assess neuropathy symptoms in the hands or arms, while items 7 to 12 assess the same symptoms in the legs and feet. Each question has three possible responses that range from; not affected, affected but not prevented, to prevented. The ONLS is calculated by adding the arm scale total and the leg scale total. The final score can range from 0 (no disability) to 12 (maximum disability). Acceptable responsiveness was shown with the ONLS (Graham, & Hughes, 2006).

Procedures

Patients from one outpatient facility were included in this study. After permission was obtained from the facility to include patients in the study (Appendix C), the proposal and permission letter were submitted to the USF Institutional Review Board for the Protection of Human Subjects (Appendix D). Following approval, clinic staff identified patients who reported numbness and tingling in their hands and/or feet. The study was explained to the patients by the primary investigator and questions answered. The patients signed the informed consent (Appendix E), a copy of the informed consent was given to the patient, and he or she was asked to complete the study forms. The BDI-SF was completed by the patient and the ONLS was administered by the primary investigator. The primary investigator asked the questions on the ONLS and the patient

answered based on self-perception. Family members were present during the interview with some of the study participants.

Data Analysis

The level of depression symptomatology and the limitations from peripheral neuropathy symptoms experienced by cancer patients were statistically analyzed using means and standard deviations. The relationship between depressive symptoms and limitations of peripheral neuropathy in chemotherapy patients were analyzed using Pearson correlation.

Chapter Four Results, Discussion, and Conclusions

This chapter presents the data collection process and the results. The significance of the study, the results, and the relevance to nursing are also discussed.

Results

The sample included 24 adult participants. Twenty-eight patients were approached and four were excluded because of diabetes or diabetic neuropathy. Age range was 45-87 with the average participant age of 65 years. One participant was 100 years old. Of the 24 patients, 37.5% of them were on a single agent taxane-based drug, 37.5% of patients were on a combination of a taxane-based drug with a platinum based drug, 16.6% of patients were on a plant alkaloid, and 8.3% were on a combination of a taxane-based and a non-neurotoxic chemotherapy drug. All patients had some symptoms of PN. The sample was made up of 66.6% females, and 92% were Caucasian. (Table 1)

Beck Depression Inventory-Short Form (BDI-SF)

The BDI-SF is a patient self-report scale. Possible scores range from 0 to 36 where 0 to 10 is not depressed, 11 to 19 is depressed and greater than or equal to 20 is very depressed. In this study the mean score was 4.125. The lowest score reported was one and the highest score was 12. There was only one reported score of 12. (Table 2)

Overall Neuropathy Limitations Scale (ONLS)

The ONLS scale is calculated by adding the arm scale total and the leg scale total. The final score can range from 0 (no disability) to 12 (maximum disability). In this

sample of 24 adults, the mean score was 2.2. The lowest score reported was zero and the highest score was five. (Table 2)

Table 1. Frequencies and Percentages of Descriptive Demographic Data

Descriptive Demographic	Frequency	Percentage
Ethnicity		
Caucasian-Non-Hispanic	22	92%
Caucasian-Hispanic	2	8%
Gender		
Male	8	33.3%
Female	16	66.6%

Table 2. Means, Standard Deviations, and Ranges for Depression and Neuropathy Scores

Variable	N	Possible Range	Sample Range	Mean	Standard Deviation
Beck Depression Inventory	24	0-36	1-12	4.1	2.7
Overall Neuropathy Limitations Scale	24	0-12	0-5	2.2	1.5

Discussion

Beck Depression Inventory-Short Form (BDI-SF)

The BDI-SF is short, and easy to read for patients. None of the participants voiced confusion over any of the questions. On average it took patients three minutes to

complete the short form. The scores overall were low. With a possible range of 0 to 36 the mean score was 4.1. These results are not consistent with earlier studies reviewed. Tolle et al. (2005) found that patients with peripheral neuropathy were so depressed they required medications for anxiety, depression and sleep disturbances.

There are some limitations of the study. The small sample size, due to time limitations, may have excluded some patients with worse symptoms. Also, patients completing the form in the presence of loved ones may not have been truthful or honest with their answers. Some patients do not want their family members to know if they are having emotional difficulties. These limitations may have contributed to the low scores.

Overall Neuropathy Limitations Scale (ONLS)

The ONLS is a short survey. It was administered to the patient by the primary investigator. On average it took patients five minutes to complete the scale.

With a possible range from 0 to 12 the mean score was 2.2. Patients with minimal neuropathy symptoms were able to participate in the study, which may account for some of the low scores. Patients had received an average of 5.9 cycles of chemotherapy, which is a sufficient amount of time for neuropathy symptoms to present. Scores might be higher if symptom severity were measured instead of interference with activity. Also, the ONLS was administered by asking the patient about interference with the various activities. Scores might have differed if the primary investigator were to observe the patient doing the activities instead of relying on self-report.

Relationship Between Peripheral Neuropathy and Depression

The patients in this study did not show a significant relationship between their neuropathy limitations and depression. Scores were low on both measures. This may

have contributed to the lack of correlation. These findings were not consistent with previous studies.

Conclusions

A study might be done in the future with a few changes. First, the sample size should be increased. This may be improved by collecting data over a longer period of time. This would allow for a wider variety of patients with a wider array of physical and mental symptoms. And second, the search criteria should include only patients with a grade two or above PN. Potentially, these changes would increase scores and result in more significant results.

It is important for nurses to understand the physical and mental effects that chemotherapy can have on patients. Peripheral neuropathy can manifest in many different ways and the limitations of ability to perform activities of daily living can be devastating. It makes sense that the loss of autonomy would cause some depressive symptoms. It is for this reason that patients need early detection of symptoms and supportive care throughout chemotherapy treatment.

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Appendices

Appendix A: Beck Depression Inventory-Short Form

BECK DEPRESSION INVENTORY SHORT FORM

- b My appetite is not as good as it used to be.
c My appetite is much worse now.
d I have no appetite at all any more.

Instructions:

This is a questionnaire. On this questionnaire are groups of statements. Please read the entire group of statements in each box. Then pick out the one statement in that group that best describes the way you feel **TODAY**, that is, right now. Tick beside the statement you have chosen. If several statements in the group seem to apply equally well, **tick each one**.

BE SURE TO READ ALL THE STATEMENTS IN EACH GROUP BEFORE MAKING YOUR CHOICE.

1.
a I do not feel sad
b I feel sad or unhappy.
c I am unhappy or sad all of the time and I can't snap out of it.
d I am so unhappy or sad that I can't stand it
3.
a I do not feel like a failure.
b I feel I have failed more than the average person.
c As I look back on my life all I can see is a lot of failures.
d I feel I am a complete failure as a person (parent, husband, wife).
5.
a I don't feel particularly guilty.
b I feel bad or unworthy a good part of the time.
c I feel quite guilty.
d I feel as though I am very bad or worthless.
7.
a I don't have any thoughts about harming myself.
b I feel I would be better off dead.
c I have definite plans about committing suicide.
d I would kill myself if I could.
9.
a I make decisions about as well as ever.
b I try to put off making decisions
c I have great difficulty in making decisions.
d I can't make decisions any more
11.
a I can work about as well as before.
b It takes extra effort to get started at doing something.
c I have to push myself very hard to do anything.
d I can't do any work at all.
13.
a My appetite is no worse than usual.

2.
a I am not particularly pessimistic or discouraged about the future.
b I feel discouraged about the future.
c I feel I have nothing to look forward to.
d I feel that the future is hope-less and that things cannot improve.

4.
a I am not particularly dissatisfied.
b I don't enjoy things the way I used to.
c I don't get satisfaction out of anything any more
d I am dissatisfied with every-thing.

6.
a I don't feel disappointed in myself.
b I am disappointed in myself.
c I am disgusted with myself.
d I hate myself.

8.
a I have not lost interest in other people.
b I am less interested in other people than I used to be
c I have all of my interest in other people and have little feeling for them
d I have lost all of my interest in other people and don't care about them at all.

10.
a I don't feel I look any worse than I used to.
b I am worried that I am looking old or unattractive.
c I feel that there are permanent changes in my appearance and they make me look unattractive.
d I feel that I am ugly or repulsive looking.

12.
a I don't get more tired than usual
b I get tired more easily than I used to.
c I get tired from doing anything.
d I get too tired to do anything.

Score: a=0, b=1, c=2, d=3

Score total: 0-10 =not depressed

12-18= depressed

20+ =very depressed **ACTION!**

Name:

Date:

Scorer:

JAAF January 2007

<http://www.sadness101.com/beck.html>

Appendix B: Overall Neuropathy Limitations Scale

OVERALL NEUROPATHY LIMITATIONS SCALE (ONLS)

Instructions: The examiner should question and observe the patient in order to determine the answers to the following questions. Note should be made of any other disorder other than peripheral neuropathy which limits function at the foot of the page.

ARM SCALE

Does the patient have any symptoms in their hands or arms; e.g. Tingling, numbness or weakness? Yes
No

Is the patient affected in their ability to:	Not affected	Affected but not prevented	
Prevented			
Wash and brush their hair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Turn a key in a lock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use a knife and fork together	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do or undo buttons or zips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dress the upper part of their body excluding buttons or zips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If all these functions are prevented can the patient make purposeful movements with their hands or arms?
Yes No

Arm Grade

0= Normal

1= Minor symptoms in one or both arms but not affecting any of the functions listed

2= Disability in one or both arms affecting but not preventing any of the functions listed

3= Disability in one or both arms preventing at least one but not all functions listed

4= Disability in both arms preventing all functions listed but purposeful movement still possible

5= Disability in both arms preventing all purposeful movements

SCORE=_____

LEG SCALE

	Yes	No	N/A
Does the patient have difficulty running or climbing stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the patient have difficulty with walking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does their gait look abnormal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How do they mobilize for about 10 meters (33 feet)?			
Without aid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
With one stick or crutch or holding to someone's arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
With two sticks or crutches or one stick or crutch holding onto someone's arm or frame	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
With a wheelchair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If they use a wheelchair, can they stand and walk 1 meter with the help of one person?

If they cannot walk as above are they able to make some purposeful Movements of their legs; e.g. reposition legs in bed?

Does the patient use ankle or foot braces?

Leg Grade

0= Walking/climbing stairs/running not affected

1= Walking/climbing stairs/running is affected, but gait does not look abnormal

2= Walks independently but gait looks abnormal

3= Requires unilateral support to walk 10 meters (stick, single crutch, one arm)

4= Requires bilateral support to walk 10 meters (sticks, crutches, crutch and arm, frame)

5= Requires wheelchair to travel 10 meters but able to stand and walk 1 meter with the help of one person

6= Restricted to wheelchair, unable to stand and walk 1 meter with the help of one person, but able to make some purposeful leg movements

7= Restricted to wheelchair or bed most of the day, unable to make any purposeful movements of the legs

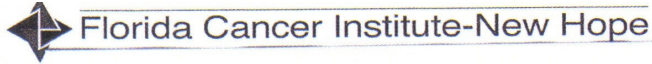
Overall Neuropathy Limitations Scale=arm scale (range 0 to 5) + leg scale (range 0 to 7)

Range 0 (no disability) to 12 (maximum disability)

TOTAL

SCORE=_____

Appendix C: Letter of Approval Florida Cancer Institute-New Hope



MEDICAL ONCOLOGY

- Jorge Ayub, M.D.
- Richard R. Caradonna, M.D.
- Mary Manlei Li, M.D., Ph.D.
- Vikas Malhotra, M.D.
- Gerald J. Robbins, M.D.
- Joseph Sennabaum, M.D.
- Thomas Tang, M.D.
- Gail Lynn Shaw Wright, M.D., F.A.C.P., F.C.C.P.
- Patrick V. Acevedo, M.D.
- Mamta Choksi, M.D.
- Cynthia L. Jensen, D.O.
- Joseph D. Rosen, M.D.

Facility Consent

Florida Cancer Institute-New Hope

I hereby consent to let USF nurse practitioner student Melissa Thebeau, RN, OCN conduct research here for her thesis study entitled, "The Correlation between Peripheral Neuropathy and Depression in Chemotherapy Patients". I understand that the study requires patients to complete two brief surveys. Melissa will be speaking with patients individually in the infusion room and may help patients complete these surveys. In return, the student will present her finding of the completed study to our facility.

RADIATION ONCOLOGY

- Sawsan G. Bishay, M.D.
- Larry Gandle, M.D.
- Lawrence D. Hochman, D.O.
- Arthur Matzkowitz, M.D.
- Gerald Sokol, M.D.

Roberta Baker _____ 1-7-10
Signature Date

Nursing Supervisor _____
Title

PALLIATIVE CARE

- Howard Glickman, M.D.

Melissa Thebeau _____ 1-7-10
Student Signature Date

NURSE PRACTITIONER

- Elizabeth Moran, A.R.N.P., A.O.C.N.

Appendix D: Letter of Approval USF Institutional Review Board



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

March 19, 2010

Melissa Thebeau,
College of Nursing

RE: **Expedited Approval** for Initial Review
IRB#: Pro00000265
Title: Peripheral Neuropathy and Depression

Dear Melissa Thebeau:

On 3/18/2010 the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol. Please note that your approval for this study will expire on March 18, 2011.

Approved Items:
Protocol Document(s):

[Thesis Proposal](#) 3/14/2010 9:21 PM 0.01

Consent/Assent Document(s):

[Informed Consent.pdf](#) 3/19/2010 11:14 AM 0.01

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

Appendix E: Informed Consent



Informed Consent to Participate in Research

Information to Consider Before Taking Part in this Research Study

IRB Study # Pro00000265

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called:

The Correlation Between Neuropathy Limitations and Depression in Chemotherapy Patients.

The person who is in charge of this research study is Melissa Thebeau, RN, OCN. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be done at Florida Cancer Institute-New Hope in New Port Richey, FL.

Purpose of the study

The purpose of this study is to:

- The purpose of this study is to find a correlation between chemotherapy-induced peripheral neuropathy and depression in chemotherapy patients. Peripheral Neuropathy is nerve damage in your arms and legs and can cause pain numbness and tingling in those body parts.
- The study is being conducted by a USF graduate nursing student. All data collection and analysis will be overseen by a USF instructor.

Study Procedures

If you take part in this study, you will be asked to:

- 1) Sign this informed consent stating voluntary willingness to participate in the study.
- 2) Complete the two brief questionnaires: The Beck Depression Scale and the Overall Neuropathy Limitations Scale.
- 3) The questionnaires will be completed in the chemotherapy infusion room.
- 4) This one visit is all that is required for this study. No follow-up visits or phone calls will be made.
- 5) No audio or videotaping will be used. All forms are confidential and do not contain any personal demographic information.
- 6) If serious depression levels are found, patient may be referred to appropriate resources.

Alternatives

You have the alternative to choose not to participate in this research study.

Benefits

The benefit of this study includes evaluation of your depression status. If depression is found, referral to appropriate resources may be made.

Risks or Discomfort

Risks in this study include any personal discomfort during the interview used to complete the depression survey.

Compensation

We will not pay you for the time you volunteer while being in this study.

Conflict of Interest Statement

There is no conflict of interest involving the principal investigator in this study.

Privacy and Confidentiality

We must keep your study records private and confidential; however, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.) These include:
 - The University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
 - The Department of Health and Human Services (DHHS).
- Confidentiality may be broken if there is suspicion of threat of harm to self or others. This information would be found during the completion of the Beck Depression Inventory.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

New information about the study

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call the Melissa Thebeau, RN, OCN, primary investigator at 727-505-8393.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the form, if the following statements are true.

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study