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The Experience of Fatigue and Quality of Life in Patients with Advanced Lung Cancer

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The Experience of Fatigue and Quality of Life in

Patients with Advanced Lung Cancer

by

Andrea Shaffer

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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Dedication

I would like to thank Dr. Cindy Tofthagen and Dr. Susan McMillan for their advisement, unyielding encouragement, and countless hours spent assisting me on staying on track. I am grateful to Dr. Joan Gregory for being ever present and a bright, positive influence during my experience. To my husband, Paul, I thank you for all of your support and love during this five year journey. I must recognize my parents, Ron and Ilse, for their love, patience, and willingness at a moment's notice to be available to watch my children or doing anything else that would allow me to pursue this endeavor. Last, but not least, I need to thank my wonderful colleagues, especially Deborah Boyette and Dianne Paiva, for always being there, for moral support, and covering my work so that I could complete my education. You are the best coworkers and friends one could hope for and I am truly blessed.

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Cancer

Andrea Shaffer

ABSTRACT

Fatigue is the most prevalent and distressing symptom experienced by
patients with advanced lung cancer and especially among those patients
undergoing therapy. Advanced lung cancer and its associated symptoms can
significantly impact the quality of life (QOL) of those who have the disease.   The
primary purpose of this study was to measure fatigue levels, characterize the
fatigue experience, and assess for gender differences in perceptions of fatigue
and QOL in patients with advanced lung cancer receiving chemotherapy. The
secondary purpose of the study was to examine practice patterns in the
ambulatory setting regarding the routine assessment of fatigue.

The study was a secondary analysis of a larger study being conducted in
the ambulatory clinics of a large, National Cancer Institute-designated
comprehensive cancer center. The study sample consisted of fifty advanced
lung cancer patients, 25 men and 25 women. Two self-report questionnaires, the
Short-Form 36® (SF-36) Acute Version 1 and Fatigue Symptom Inventory (FSI),
were completed by the subjects after receiving a single cycle of chemotherapy.

A chart audit of the 50 subjects was performed assessing for provider documentation of fatigue assessment and method(s) utilized.

Subjects ranged in age from 40 to 80, with a mean age of 62.4 years. Of the 50, 26 patients had Stage IV non-small cell lung cancer. A majority of the patients were receiving chemotherapy alone and had not received prior chemotherapy.

The results of this study revealed no significant gender differences in fatigue severity, frequency, or interference levels. The study results also failed to confirm gender differences in QOL measures. The chart audit did reveal that the providers in this study did not consistently assess and document fatigue levels, with the nurses documenting less frequently than the physicians.

The results of this study did suggest that fatigue levels and QOL are problematic for patients treated for lung cancer. In an effort to better assist patients and tailor plans of care, it is vital that practitioners, especially nurses, assess for fatigue in advanced lung cancer patients.

Chapter One

Introduction

Fatigue is a symptom that every person will experience at least once, but usually multiple times during his or her life. In the healthy person, fatigue begins when the individual physically exerts, experiences stress, or lack of sleep, and serves as a protective function by signaling the person to restore energy by resting. A good night's sleep or a few hours of relaxation will generally revive a healthy individual to a normal level of functioning (Yarbro, Frogge, & Goodman, 2005). Fatigue as a result of cancer and its treatments differs from acute fatigue because patients continue to suffer feelings of weakness and tiredness despite rest (Byar et al., 2006).

Fatigue is the most prevalent and distressing symptom experienced by patients with cancer and undergoing therapy. Individuals with cancer were the first to call fatigue a cancer-related symptom. It is estimated that fatigue is reported by 60 to 100 percent of individuals with cancer during their course of disease and associated treatment (Yarbro et al., 2005). This symptom affects 70 to 95 percent of patients receiving chemotherapy, radiation therapy, or biotherapy and lingers in 17 to 40 percent of disease-free cancer survivors (Lavdaniti et al., 2006).

Fatigue is a multidimensional, subjective experience with physiologic, psychological, functional, and social consequences (Donovan & Ward, 2005). The etiology of fatigue is multifactorial in that it may be related to the disease itself, to sleep disturbance, to concurrent systemic issues such as anemia or pain, or to emotional distress (Madden & Newton, 2006). Fatigue is characterized by subjective signs such as feelings of tiredness, muscle weakness, negative mood, loss of alertness, and the perception of interference with daily living activities (Madden & Newton, 2006; Yarbro et al., 2005). The objective manifestations of fatigue can include weight loss, decreased energy, apathy, anemia, weakness, lack of motivation, decreased attention, excessive sleepiness, or alterations in sleep patterns (Yarbro, et al., 2005). Fatigue varies in unpleasantness, duration and intensity (Byar et al., 2006).

Lung cancer is the second most common cancer diagnosis and is the leading cause of cancer mortality worldwide. In the United States, the five-year survival rate across all stages of lung cancer remains at approximately 14% and has not changed significantly in several decades. The most common symptoms reported by newly diagnosed lung cancer patients at any stage and for those undergoing therapy for advanced disease are fatigue along with pain, anorexia, insomnia, cough and dyspnea (Tanaka et al., 2002). Given this information, it is vital to improve the quality of life in this patient population and affect the single most common symptom experienced.

Quality of life (QOL) is a multidimensional phenomenon that can often be impacted by the experience of living with lung cancer. Lung cancer can

positively or negatively influence the physical, social, psychological, and spiritual dimensions of daily living. Patients with lung cancer report the greatest amount of psychological stress in comparison with other cancer patients. Disturbances in QOL are vital to assess during the entire disease continuum (Sarna et al., 2005).

Lung cancer and its associated symptoms have a significant impact on quality of life of those who have the disease. However, there has been little research about how gender affects the symptom experience of people with lung cancer (Hoffman et al., 2007). According to the Centers for Disease Control and Prevention (2007), lung cancer is the second most common cancer among white, black, Asian/Pacific Islander, American Indian/Alaska Native, and Hispanic men. Lung cancer is the second most common cancer among white and American Indian/Alaska Native women in the United States, and mortality rates in women are nearly twice that of breast cancer. Lung cancer death rates for U.S. women are among the highest in the world. There has been a progressive swing in lung cancer demographics with a significant increase in women patients in the last two decades (Loevgren et al., 2007).

Fu and colleagues (2005) sought to further characterize the effect of gender on the clinical features and survival patterns of patients with lung cancer by analyzing data collected from the National Surveillance, Epidemiology, and End Results Database (SEER). They found that women were diagnosed at an earlier age than men, raising the question of gender-specific differences in susceptibility to carcinogens. However, women statistically have better

outcomes than men at all stages of disease possibly because of hormonal influences.

Despite the fact that the demographics of lung cancer are changing from a predominantly male disease, most studies of symptoms and/or quality of life (QOL) are based on Caucasian, middle-income men with advanced lung cancer. Some studies have suggested that the symptom experiences of men and women with lung cancer are different and that women report more and a greater intensity of symptoms than men (Loevgren et al., 2007). Also, role differences often exist between men and women, which could significantly impact the perception of intensity of symptoms and greatly affect quality of life.

At the 2007 Oncology Nursing Society 32nd Annual Congress, attendees for a special symposium entitled "Cancer-Related Fatigue: The 6th Vital Sign" were surveyed about practice patterns in their particular settings and about their experience in assessing cancer-related fatigue (CRF). The results revealed that approximately one-third of patients with cancer may not be routinely assessed for fatigue and of those who are assessed for CRF, likely only half of the acquired information is being documented. The nurses cited barriers to routine assessment of this symptom in their practices as time constraints, lack of an appropriate assessment tool, and lack of an appropriate documentation tool (Given, 2008).

Statement of Problem

An increasing amount of research is available documenting the experience of fatigue and its effect on quality of life in women with breast cancer

during treatment and in survival phases. Few studies exist that have examined potential gender differences in the experience of fatigue and perceived impact on QOL in patients with advanced lung cancer receiving chemotherapy. As the goal of palliative chemotherapy is symptom control and a majority of lung cancers are diagnosed in advanced stages, it is imperative that the extent and significance of the fatigue experience be further defined. The primary purpose of this study was to measure fatigue levels, characterize the fatigue experience, and assess for gender differences in perceptions of fatigue and QOL in patients with advanced lung cancer receiving chemotherapy. The secondary purpose of this study was to examine practice patterns in the ambulatory setting regarding the routine assessment of fatigue. As fatigue is identified as a prevalent and distressing issue in cancer populations, it is important that clinicians are assessing for fatigue and determining to what extent it may be affecting overall quality of life.

Research Questions

1. What are the reported fatigue levels in advanced lung cancer patients who have received a single cycle of chemotherapy?

2. Are there gender differences in the severity, frequency, and total interference of the fatigue experience?

3. Are there gender differences in quality of life in advanced lung cancer patients?

4. How often are providers assessing lung cancer patients for fatigue and documenting information obtained?

5. Which method(s) are utilized to perform fatigue assessment in lung cancer patients?

Definition of Terms

For the purposes of this study, fatigue and QOL are defined as:

1. Fatigue is a multidimensional concept that includes physical, psychological, social and spiritual aspects and is characterized by feelings of weakness and tiredness not fully relieved by rest (Byar et al., 2006).

2. Quality of life is defined as a multidimensional, intricate concept that blends the physical, functional, psychological, and social well-being of each individual. (Losito et al., 2006).

Significance to Nursing

Fatigue is a very important concept for healthcare professionals to examine and attempt to understand. Fatigue is a problem that can lead to other physiologic and psychologic symptoms that collectively affect every aspect of a patient's life and thereby impact overall QOL.   Studies have already indicated gender differences in survival rate and susceptibility in people with lung cancer. Few studies have defined gender differences in the symptom experiences of people with lung cancer (Hoffman et al., 2007). Therefore, it is important to elucidate this information as a first step in tailoring interventions to the particular needs of the defined population. The assessment and documentation of fatigue levels and recommended management techniques by practitioners is vital to making an impact on this very distressing cancer-related symptom.

Chapter Two

Review of Literature

Fatigue is the most frequently reported symptom experienced by patients with cancer across the disease continuum. Fatigue is distressing, greatly impacts quality of life, and profoundly effects patients' abilities to function in routine roles and activities. The severity of the fatigue experience can delay treatments, persist for months or years, and may be predictive of shorter survival in particular cancer populations (Beck, Dudley & Barsevick, 2005). Hoffman et al. (2007) noted that few studies have targeted gender differences in the symptom experiences of patients with lung cancer, and the results of the studies have been mixed.

Quality of Life and Fatigue

In 2001, Okuyama et al. conducted a study to determine the prevalence of interference of daily activity due to fatigue in advanced lung cancer patients, the correlated factors, and methods to detect at risk patients. The study accrued 157 subjects with advanced stage or recurrent disease, of which the majority were male, from ambulatory patients at two large academic centers in Japan.

The researchers utilized several instruments to ascertain the information they were seeking including the Cancer Fatigue Scale (CFS), the Fatigue Numerical Scale (FNS), and a self-administered questionnaire asking if fatigue

had interfered with any of seven domains of their activities of daily living. The

CFS is a 15-item self-rating scale for assessing fatigue in cancer patients that

consists of three subscales and is modeled to assess the multi-dimensional

nature of fatigue. Items are rated on a Likert-type scale with higher scores

indicating more severe fatigue. The FNS is a simplistic tool utilized for assessing

fatigue intensity and patients rate their fatigue experience on an 11-point scale.

The investigators also assessed a broad range of biopsychological factors,

including cancer information and previous history of anti-cancer therapy,

psychological distress, and demographical and social support status using

medical record data, a self-administered questionnaire, and structured interview

(Okuyama et al., 2001).

The investigators found that 81.5% of patients experienced some degree

of fatigue and that one-third of patients reported that fatigue had interfered with

physical activities such as walking or normal work. One fifth of the patients

reported that fatigue had interfered with emotional activities such as mood or

enjoyment of life and half of the patients were found to have clinical fatigue.

Depression was also found to be a correlated factor for fatigue (Okuyama et al.,

2001). Limitations of this study are the lack of gender representation and

therefore, lack of ability to generalize results to entire population of advanced

lung cancer patients.

Tanaka and colleagues (2002) investigated how often fatigue, dyspnea,

and pain interfered with daily living activities, whether any differences existed in

the characteristics of these symptoms regarding impact on daily life activities,

and whether an 11-point numerical scale was appropriate for screening for those symptoms interfering with at least one daily life activity in ambulatory patients with advanced lung cancer. The study accrued 171 patients and again a majority of the patients were male. Subjects were recruited from ambulatory lung cancer clinics in two large academic centers in Japan.

The researchers utilized a questionnaire to be completed by the subjects at home and then returned in the mail. If any items were left blank, telephone inquiry was used to obtain missing data. The severity of dyspnea, pain, and fatigue were evaluated with an 11-point numerical scale with the higher the rating correlating with a greater symptom distress. Another questionnaire, which was a modified version of the Brief Fatigue Inventory (BFI), was used to assess the impact of the three symptoms on daily living activities in the previous 24 hours. The responses were either "presence" or "absence" of interference. Demographic information and medical information were obtained from medical record review (Tanaka et al., 2002).

The investigators found that fatigue interfered with at least one daily life activity in 52% of subjects and mood and enjoyment were disturbed in approximately 20% with fatigue rated as severe as a seven. Dyspnea interfered with at least one daily life activity in 55% of subjects, but subjects did not experience as significant a disturbance in mood and enjoyment. Limitations of the study were that 74% of subjects had an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of one, which is slightly higher than most

patients in this population, and the tools utilized were not properly validated and confirmed (Tanaka et al., 2002).

Brown, McMillan, and Milroy in 2005 sought to explore the relationship between fatigue, physical function, the systemic inflammatory response, and psychological distress in patients with advanced lung cancer. The study accrued a total of 55 patients, 38 lung cancer patients and 15 healthy subjects. Of the 38 lung cancer patients, 23 were men and 15 were women. The lung cancer patients were those diagnosed with locally advanced or metastatic disease and recruited from two specialty palliative care centers and an associated hospital in the United Kingdom. The healthy volunteers were age-matched and gender-matched.

The control group and patient group were assessed for fatigue, weakness, anthropometry, physical function, and psychological distress and several questionnaires were utilized to assess fatigue, weakness, and psychological distress. The authors used the Functional Assessment of Chronic Illness Therapy-Fatigue scale (FACIT-F) to measure fatigue and this tool is a 13-item subscale of the FACIT-F questionnaire that has subjects score each item on a zero to four scale (not at all to very much). A low total score represents a high level of fatigue. The subscale assesses quality of life in cancer patients experiencing fatigue and other anemia-related symptoms. Weakness was measured using a simple 10-cm visual analogue scale which ranged from "I don't feel weak at all" to "I couldn't feel any weaker". Psychological distress was measured using the Hospital Anxiety and Depression (HAD) scale and this is a

14-item self-report questionnaire intended to measure anxiety and depression. The subjects were asked to score the answer that came closest to how they had been feeling in the previous week on a scale of zero to three with a higher score suggestive of psychological distress (Brown, McMillan & Milroy, 2005).

The results revealed that patients with advanced lung cancer had higher levels of weakness and fatigue and increased psychological distress as compared to the control group. The authors subdivided the group of cancer patients on the basis of fatigue and found that fatigue was clearly associated with poor physical function and more psychological distress (Brown, McMillan & Milroy, 2005). The comparison to the healthy population was interesting, however, likely not necessary as it is intuitive that the cancer population will report more symptoms and higher severity scores.

Dagnelie and colleagues. (2007) conducted a cross-sectional study to quantify the impact of fatigue, relative to other QOL domains, on overall QOL in lung and breast cancer patients preceding curative radiotherapy. Their interest derived from lack of studies on this issue. The study accrued a total of 64 patients with 100% of the breast cancer patients being women and 45% of the lung cancer patients being women.

The investigators used the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) which is a 30-item cancer-specific core questionnaire that contains five function subscales, three symptom subscales, and two single items assessing global health and "overall" QOL, and a number of single items addressing various symptoms and

believed financial impact. Subjects were asked to complete the EORTC QLQ-C30, as well as a demographic profile, prior to beginning radiotherapy (Dagnelie et al., 2007).

The investigators found that EORTC QLQ-C30 scores revealed considerable impairment in global health status and overall QOL, especially in lung cancer patients. Also, significant impairment was noted for the subscales physical, role and emotional functioning, and for the symptom subscales fatigue, dyspnea, pain, insomnia, and appetite loss. Lung cancer patients reported being significantly more tired than breast cancer patients. There was a distinct correlation between level of fatigue and perceived overall QOL (Dagnelie et al., 2007). A limitation of this study is the inability to generalize these results into advanced stages of lung cancer as the subjects in this trial were receiving curative radiotherapy.

Bozcuk and colleagues in 2006 were interested in exploring disease and treatment factors that can affect QOL that have not previously been thoroughly investigated in patients with metastatic non-small cell lung cancer receiving chemotherapy. The study acquired 50 patients with 46 men and only 4 women. Thirty-seven of the patients were receiving first line chemotherapy and thirteen were receiving second line. All subjects had either unresectable stage three or stage four disease and were seen in ambulatory medical oncology clinics.

The authors also utilized the EORTC QLQ-C30 questionnaire to assess the various aspects of QOL. The questionnaire was completed prior to the first cycle, on day seven, and after the completion of the second cycle. The

investigators gathered demographic, disease, and treatment data from medical record review (Bozcuk et al., 2006).

The study results proved quite interesting. The authors found that baseline QOL affects the change in QOL on chemotherapy in that those patients with a starting global QOL score less than or equal to 50 saw an increase in global QOL and physical functioning and a decrease in fatigue after two cycles of chemotherapy. Conversely, those patients with a starting global QOL score greater than 50 saw a decline in global QOL and physical functioning, but an increase in fatigue. Also, patients receiving second line chemotherapy reported less fatigue while on chemotherapy than those patients receiving first line chemotherapy (Bozcuk et al., 2006). A definite limitation of this study was the few number of women represented in the study sample.

Gender and Fatigue

Sarna and Brecht (1997) performed an exploratory study, combining two studies of women with advanced lung cancer, with the purpose of investigating the underlying cluster of distressing symptoms experienced by women with advanced lung cancer and exploring the differences in symptoms among clinical and demographic variables. The study looked at a combined total of 60 women accrued in oncology clinics, private practices, and oncology units. Forty were from a previous descriptive study looking at women with any stage of disease and twenty were from a current longitudinal trial looking at women with advanced stage lung cancer. The authors performed a secondary analysis of the forty women from the previous study. The women ranged in age from 33 to 80 years,

were eight-seven percent Caucasian, the majority were married and had non-small cell lung cancer in advanced stages.

The Symptoms Distress Scale (SDS) is a 10-item self-report scale developed for assessing cancer-related symptoms, but for this study was modified to include 13 items pertinent to lung cancer patients. Items are reported on a Likert-type scale with rates from one to five and five represents the most distress. Clinical variables assessed included physical function, presence and mode of treatment, presence of distant metastases, smoking status, and presence of comorbid disease which was obtained from Karnofsky Performance Status rating and medical record data. Demographic variables included race or ethnicity, age, marital status, employment status, income, and education which were collected from a demographic form completed by the patients (Sarna & Brecht, 1997).

Sarna and Brecht (1997) found that fatigue, negative outlook, frequent pain, and insomnia were the most prevalent and the most seriously rated symptoms. There were no differences reported in symptom distress by the presence of distant metastases, comorbid disease, histologic type of lung cancer, marital status, education, income, or smoking status. Limitations of this study were small sample size in that essentially only 20 women were actively evaluated by the study instrument and lack of comparison of women to men to ascertain whether there were gender differences in symptom experience.

Sarna et al. in 2005 conducted a prospective, cross-sectional, descriptive study to describe the quality of life (QOL) in women living with non-small cell lung

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cancer, describe the characteristics of meaning of illness (MOI), and explore the demographic, clinical, health status, and MOI correlates of QOL. The study collected data from 217 women, predominantly Caucasian, recruited from multiple clinical sites in the western, eastern, and southern regions of the United States. All study participants had been diagnosed at least six months and less than five years with non-small cell lung cancer.

The investigators utilized several instruments including the QOL Scale-Patient Version (QOL-Patient) and the Short Form-36 Item (SF-36). The QOL-Patient is a 41-item questionnaire that was used in this study as a cancer-specific measure of QOL. Each item uses a Likert-type scale on an 11-point range and consists of four subscales addressing physical, social, psychological, and spiritual well-being. Subjects responded to questions based on how their cancer experience affected their quality of life. The SF-36 was used as a generic measure of health-related QOL and is a 36-item self-report questionnaire that evaluates physical functioning, bodily pain, role limitations caused by physical health, role limitations caused by emotional health, emotional well-being, social functioning, vitality and fatigue, and general health perceptions. Scores range from 0 to 100 one each subscale and higher scores indicate better QOL. Meaning of illness (MOI) was assessed using eight cards with individual statements describing illness in positive or negative terms. All eight cards were placed in front of the subject at one time and the subject was asked to choose the card the most represented her view of her illness. The investigators also

collected data on health status, depressed mood, demographics, and clinical variables (Sarna et al., 2005).

The researchers found that women reported serious levels of fatigue, substantial disruptions in psychological well-being, and a strong relationship between health status and physical QOL. One limitation of the study was that of the 217 subjects accrued, 184 were Caucasian, thereby making it difficult to generalize to all the population of women with lung cancer. The investigators did only include those subjects with non-small cell lung cancer; however, this is of little consequence as the majority of patients with lung cancer have this histologic type (Sarna et al., 2005).

Hoffman et al. (2007) studied the relationships among pain, fatigue, insomnia, and gender while controlling for age, comorbidities, and stage of cancer. The study was a secondary analysis of a single-blinded, randomized clinical trial of people with cancer sponsored by the National Cancer Institute and the National Institute for Nursing Research and the researchers selected only data on lung cancer patients obtained from the first interview at the time of entry into the trial.

Participants were accrued from two community oncology programs and two comprehensive cancer centers. The analysis was completed on 80 patients ranging from age 41 to 83 years and mostly married Caucasians. The analysis was divided nearly even at 55% men and 45% women (Hoffman et al., 2007).

The participants were exposed to a 10-session nursing intervention that lasted 20 weeks. Symptoms were assessed utilizing the Cancer Symptom

Experience Inventory which is a self-report instrument of 15 symptoms related to cancer or its treatment. For this study, the variable assessing the frequency of fatigue, pain, and insomnia was dichotomized to measure the duration of the relationships among fatigue, pain, and insomnia in people with a new diagnosis of lung cancer with 56 days of receiving chemotherapy. Symptoms were rated on a scale from 0 to 10 with 10 indicating the greatest severity. Comorbidities were assessed using a modified version of the Comorbidity Questionnaire which assessed for the presence or absence of 14 various chronic health conditions (Hoffman et al., 2007).

The investigators found that there were no gender differences in fatigue reporting, with 98% of men reporting fatigue and 94% of women reporting fatigue. Of the three symptoms of interest to the authors, the only symptom reported with higher levels of severity for women than men was insomnia. Limitations of this study were that it was a secondary analysis and that it was difficult to ascertain whether the symptoms addressed were related to disease and treatment or to comorbidities (Hoffman et al., 2007).

Husain et al. in 2007 explored sex differences in fatigue at the end of life. The investigators hypothesized that a sex difference in fatigue exists and that sex-specific correlates lie beneath this difference. The study was a three-month longitudinal study that accrued subjects from a home palliative care program serving a major urban center. Patients had to be admitted to the palliative care program to be eligible to participate and were excluded if under the age of 18 and if cognitively impaired.

The study accrued a total of 102 patients with a fairly equal representation of each sex - 47 men and 55 women. The participants completed questionnaires at zero, one, three, five, seven, nine, and eleven weeks and the disposition of patients were followed for 12 months after completion of the study. The investigators utilized the Brief Fatigue Inventory (BFI) which is a nine-item, self-report, symptom severity and functional interference scale. The tool measures the single domain of fatigue severity and a score of greater than 3 was used as a discontinuance point to identify moderate to severe fatigue. The investigators also utilized the McGill Quality of Life (MQOL) Questionnaire which is a multidimensional tool that measures physical, psychological, support, and existential domains. Scores are reported from 0 to 10 and higher scores correlate with better QOL (Husain et al., 2007).

The authors of the study found that the prevalence of moderate to severe fatigue at week zero and over time was significantly higher in women than in men. Interestingly, no differences in MQOL scores were found between the sexes. This study was the first such study documenting that women experience a higher prevalence of fatigue and a marked fatigue severity, at least in the setting of advanced illness receiving palliative care at home. A limitation of this study was that it did not elucidate specific cancer diagnosis and therefore, did not account for specific cancer treatments (Husain et al., 2007)

Loevgren et al. (2007) initiated a study to examine the prevalence and severity of symptoms and difficulties with functioning in women and men with inoperable lung cancer. The study looked at these issues at three points close to

diagnosis, the extent to which these issues change over time, and patient characteristics that influence these issues. Loevgren et al. (2007) analyzed data generated from 159 patients, 70 women and 89 men, who had completed the EORTC QLQ-C30+ Lung Cancer13 (LC13) at baseline (T1), 1 month (T2), and 3 months (T3) after T1.

The EORTC QLQ-C30 + LC13 is a self-report health-related QOL instrument that assesses general aspects of health-related QOL through 30 items consisting of five functional scales, three symptom scales, a global health status/QOL scale, and several single items such as dyspnea and insomnia. The LC13 module assesses disease-specific symptoms, treatment-related side effects, and pain medication. Each item is evaluated on a four-point Likert scale except for the global health status/QOL items and these have responses that range from "very poor" to "excellent". However, the global health/QOL scale was not used in this study (Loevgren, 2007).

The study revealed that the most prevalent symptoms and difficulties with functioning were associated with fatigue at all time points for both women and men. However, significantly more women than men reported "feeling tense", "worried", "depressed" and more limited in work/daily activities at baseline and also reported that at T1, their physical condition or treatments interfered with their social activities and at T3, they needed to stay in the bed or in a chair for most of the day. One limitation of this study was the small sample size, but it is difficult to accrue a large sample of lung cancer patients to these studies as this group is

typically severely ill and non-random attrition and non-participation is a significant

barrier to accrual (Loevgren et al., 2007).

Fatigue Assessment

Regarding routine assessment of fatigue by clinicians, several studies

have sought to identify potential barriers from the patient, clinician, and system

perspectives. In 2002, Passik et al. conducted a clinical trial to explore patient-

related barriers to communication about fatigue according to the patient

perspective. The study recruited 200 subjects equally from multiple urban and

rural sites in the Community Cancer Care, Inc. network in Indiana. The

investigators utilized the 28-item self-report Fatigue Management Barriers

Questionnaire (FMBQ) and found that 46.7% of the subjects reported that

interventions for fatigue were not being offered as well as 43.1% stated that they

were unaware of any possible treatments for fatigue. This led the investigators to

conclude that physicians and patients seem to have reservations discussing

fatigue as a symptom of the disease and as a consequence of therapy.

Borneman et al. (2007) reported data on the phase one portion of a three

phase five year prospective National Cancer Institute (NCI) - funded clinical trial

seeking to translate the National Comprehensive Cancer Network (NCCN)

Cancer-Related Fatigue Clinical Practice Guidelines in Oncology into practice

and construct a translational interventional model that can be reproduced across

other settings. Phase one of the study examined fatigue-related patient,

professional, and system barriers that hinder routine use of NCCN guidelines

recommendations.

The trial recruited 69 patients with a known diagnosis of breast, lung, colon or prostate cancer from one medical oncology adult ambulatory care clinic at a NCI-designated comprehensive cancer center in Southern California. A chart audit was conducted to evaluate practitioner practices. The audit revealed a lack of adherence to guidelines, documentation of fatigue, and referrals for supportive care. Of note, the greatest adherence was documented for assessment of anemia at 28.99%. A significant number of the patients (66%) reported that they had never discussed their complaints of fatigue with their physician and the prevailing belief (54%) was if fatigue was important, then the physician would have initiated conversation on this subject. (Borneman et al., 2007)

Knowles et al. (2000) conducted a survey study of registered nurses working with the Department of Clinical Oncology at the Cancer Centre in Edinburgh, UK. The investigators wished to evaluate nurses' knowledge of fatigue, assessment practices, and what interventions they employed to address patient complaints of fatigue. The study revealed that cancer-related fatigue was identified as a common symptom experienced by a majority of the patients the respondents cared for and 75% of the respondents reported that they assessed for fatigue in their patient population. However, the study did not delineate the methods and depth of fatigue assessment and whether assessment of fatigue was routinely performed. Of note, nurses utilizing common grading criteria were more likely to work with patients enrolled on clinical trials.

Summary

From the review of literature, many of the studies exploring fatigue, symptom distress, and impact on quality of life in women with lung cancer specifically were conducted in the 1990s, and the state and rigor of treatment modalities, even palliative, has changed since that time. The majority of current studies examining this population have largely not been conducted in the United States so results are not necessarily generalizable to our population of women who may have different roles and concerns. Sufficient studies exist to explore the issue of fatigue and quality of life in the general lung cancer population, however, most of the participants in these trials were men, rendering the results not clearly applicable to women. Loevgren et al. (2007) speculates that a lack of knowledge about differences in symptom experiences between men and women may impede appropriate intervention from the health care system. Also noted, was a lack of trials with any interventions to address fatigue and thereby impact quality of life in this patient population.

Studies suggest that there are many barriers that hinder systematic assessment, management, and documentation of cancer-related fatigue. In an effort to breakdown these barriers, further studies of the patterns of clinician and nursing assessment of fatigue need to be completed.

Chapter Three

Methods

The purpose of this study was to measure fatigue levels, characterize the fatigue experience, and assess for gender differences in perceptions of fatigue and quality of life (QOL) in patients with advanced lung cancer receiving chemotherapy. The secondary purpose of this study was to examine practice patterns in the ambulatory setting regarding the routine assessment of fatigue. This chapter delineates the sample, measurement tools, and procedures utilized to facilitate obtaining the information sought by the researcher. The chapter ends with a description of data analysis.

Setting and Sample

This study was a secondary analysis of a larger study that was already underway in the ambulatory care clinics of a large, National Cancer Institute-designated comprehensive cancer center. This larger study had accrued over 300 patients at the time of this study and sought to examine the impact and relationships of stress management and exercise training on QOL during chemotherapy treatment. Data on fifty subjects, 25 women and 25 men, all with advanced lung cancer, was extracted and examined to achieve a representative sample of each gender to assess for any differences in fatigue severity, frequency, total interference and QOL. Participants were 18 years of age or

older; capable of speaking and reading standard English; diagnosed with advanced lung cancer; had not received intravenous chemotherapy administration in the last two months; were scheduled to receive cytotoxic chemotherapy as outpatients at the center over a period of at least 14 weeks; had an ECOG performance status of zero, one, or two; and were able to provide informed consent.

Instrumentation

Short-Form 36® (SF-36) Acute Version 1

The SF-36 is a multi-purpose, short-form health survey questionnaire consisting of 36 items. It is a self-report measure designed to assess perceived health and functioning and contains eight scales: ten physical functioning items, two social functioning items, four role limitations due to physical problems items, three role limitations due to emotional problems items, five mental health items, four energy and vitality items, two pain items, and five general perceptions of health items. Each scale uses a variety of rating formats and raw scores are converted to a standard metric. Subjects provide Likert-type responses to questions regarding perceived ability to complete activities of daily living. Each item is scored on a scale from 0 to 100 with 0 representing the worst possible health state and 100 representing the best possible health state (Jenkinson et al., 1993). The interrelatedness of the psychosocial and functional dimensions of QOL is correlated with physical functioning, and psychosocial aspects are measured in terms of social activities and relationships (Losito et al., 2006)

Reliability and validity. The SF-36 has subscale reliability coefficients ranging from 0.76 to 0.93. Content validity and construct validity have been supported in multiple QOL studies (Ware et al., 2002; Losito et al, 2006)

Fatigue Symptom Inventory (FSI)

The FSI is a 14-item self-report tool that assesses the severity, frequency, and daily pattern of fatigue, as well as its perceived interference with performance. Four items measure severity on separate 11-point scales that assess most, least, and average fatigue in the past week as well as current fatigue. Frequency is measured utilizing two separate items that assess the number of days in the past week that fatigue was felt as well as the extent of each day on average fatigue was felt. Perceived interference is measured on seven separate 11-point scales that assess the degree to which fatigue in the past week was judged to interfere with general level of activity, ability to bathe and dress, normal work activity, ability to concentrate, relations with others, enjoyment of life, and mood. Interference ratings can be added to obtain a total perceived interference score. The final item is a diurnal variation measured using a single item that provides descriptive information about daily patterns of fatigue (Jacobsen, 2004).

Reliability and validity. The FSI is an established reliable and valid measurement tool of fatigue in patients with cancer. The Cronbach's alpha coefficient ranges from 0.92 to 0.95, with convergent validity supported by significant correlations with the Profile of Mood States-Fatigue (POMS-F).

Construct validity was supported by significant correlations with life satisfaction and depression (Hann et al., 2000).

Demographic Data Form

Demographic data was gathered from existing self-report and medical record review information collected during enrollment of the subjects. Data extracted for this study included age, gender, histology, stage of disease, ECOG status, whether treatment included radiotherapy and/or biologic therapy, previous chemotherapy, marital status, ethnicity, race, educational status, employment status, occupations of both subject and spouse, and net household income.

Chart Audit Form

A chart audit form was developed to track provider assessment and documentation of fatigue levels for the 50 subjects examined in this study.   Also, method of assessment utilized was assessed. Charts were reviewed for use of any of the five most common tools of fatigue level assessment: a four-point verbal rating scale (none, mild, moderate, severe); a five-point verbal rating scale (none, mild, moderate, severe, very severe); an eleven-point numeric scale (0 is no fatigue and 10 is worst possible fatigue); a four-point numeric scale (Common Toxicity Criteria of the National Cancer Institute); and a 10cm visual analogue scale (no fatigue to worst possible fatigue). If present in the documentation, data was appropriately recorded.

<div align="center">Institutional Approvals</div>

Approval to conduct the larger study had already been obtained from the Scientific Review Committee (SRC) of the institution from which the subjects

were accrued and the University of South Florida Institutional Review Board

(IRB). Both entities are in existence to evaluate the validity of a study and to

protect the welfare of any human subjects who chose to participate in this study.

An amendment to the original study was drafted to include the chart audit that

assessed provider practice patterns of assessment and documentation of fatigue

levels and was approved by the University of South Florida IRB.

Procedures

With assistance from the researchers conducting the larger study, the

existing database was queried for an equal number of female and male subjects

with advanced lung cancer who had received at least one cycle of chemotherapy.

The subjects' FSI and SF-36 questionnaire scores at 5 to 6 weeks after a single

cycle of chemotherapy, as well as pertinent demographic data, were gathered.

Also, the medical record was reviewed for physician and nurse documentation of

fatigue levels and methods of assessment on the baseline office visit and the first

follow-up visit after a single cycle of chemotherapy.

Data Analysis

Descriptive statistics were used to analyze the demographic data including

frequencies, percentages, means, and standard deviations. Gender differences

in fatigue levels and QOL scores were analyzed for statistical significance

utilizing t-tests.   Categorical data regarding the absence or presence of fatigue

assessment by the physician and nurse was analyzed utilizing frequencies and

percentages.

Chapter Four

Results, Discussion and Conclusions

This chapter presents the findings of the study.   Included in this chapter are the results, discussion of the findings and limitations, conclusions, and recommendations for future research.

Results

The sample consisted of 50 total subjects, 25 women and 25 men. They ranged in age from 40 to 80 with a mean age of 62.4 (SD=10.1). Of the sample, 64 percent were married and 30 percent were divorced. The majority of the participants were white, representing 48 of 50 patients. Nearly half of the subjects reported some college education or specialized training while a quarter reported a high school graduate level of education (Table 1).

Table 1

Frequency and Percent of Sample Demographic Characteristics

	Variable	Frequency	Percent
Gender	Male	25	50.0
	Female	25	50.0
Marital Status	Currently	32	64.0
	Divorced	15	30.0
	Never	2	4.0
	Widowed	1	2.0
Race	White	48	96.0
	Black/African American	1	2.0
	More Than 1 Race	1	2.0
Education	Partial High School (10th & 11th)	2	4.0
	High School Graduate	12	24.0
	Partial College or Special Training	21	42.0
	College or University Grad	8	16.0
	Graduate Degree	7	14.0

The majority (n=22) of subjects were retired. Household incomes were fairly evenly distributed across a range from $20,000 up to greater than $100,000, with nine patients preferring not to respond to this particular demographic question (Table 2).

Table 2

Frequency and Percent of Employment Status and Household Income

Variable		Frequency	Percent
Employment	Retired	22	44.0
	Full-time Job	7	14.0
	Part-time Job	6	12.0
	On leave w/ pay	6	12.0
	On leave w/o pay	5	10.0
	Disabled	4	8.0
Household Income	Less than $10,000	5	10.0
	$10,000-$19,999	4	8.0
	$20,000-$39,999	10	20.0
	$40,000-$59,999	6	12.0
	$60,000-$100,000	9	18.0
	> $100,000	7	14.0
	Prefer Not to Answer	9	18.0

All of the subjects in this sample had lung cancer (n=50). Of the 50, 26 patients had Stage IV non-small cell lung cancer, 14 had stage III non-small cell lung cancer, five had limited stage small cell lung cancer, and five had extensive stage small cell lung cancer. Approximately one-third of the patients had an ECOG performance status of 0 and two-thirds had an ECOG of one. The majority of patients were receiving chemotherapy alone, with only nine receiving radiation in addition to chemotherapy and nine receiving biotherapy in addition to chemotherapy. Forty-five subjects had never had chemotherapy before while five had prior chemotherapy experience (Table 3).

Table 3

Frequency and Percent of Disease and Planned Concurrent Therapy

Variable		Frequency	Percent
Type of Ca	Lung	50	100.0
ECOG PS	1	32	64.0
	0	18	36.0
Stage	IV NSCLC	26	52.0
	III NSCLC	14	28.0
	Ltd. SCLC	5	10.0
	Ext.SCLC	5	10.0
Receiving Radiation	Yes	9	18.0
Receiving Biotherapy	Yes	9	18.0
Previous Chemotherapy	Yes	5	10.0

Fatigue Symptom Inventory (FSI)

Levels, severity, frequency, and total interference of fatigue were assessed utilizing the FSI self-report questionnaire. Overall fatigue was reported with a mean of 5.9 (SD=3.0) for the highest level in the past week and a mean of 2.1 (SD=1.9) for the lowest level in the past week. Subjects reported that fatigue occurred with a mean of 4.7 days in the past seven days. Fatigue was reported to have been present at a mean of 4.5 hours (SD=3.1) per day (Table 4).

Men reported the highest level of fatigue with a mean score of 6.4 (SD=3.1) and the lowest level with a mean of 2.4 (SD=2.0) in the week preceding the completion of the questionnaire. Women reported the highest level of fatigue with a mean score of 5.4 (SD=3.0) and the lowest level with a mean of 1.9 (SD=1.7). Frequency data revealed that out of one week, men reported fatigue with mean scores of 4.8 days and women with mean scores of 4.6 days (Table 4).

The overall, total interference scores revealed a mean of 20.3 (SD=19.9). The rate that fatigue interfered with levels of activity was reported as a mean of 3.9 (SD=3.7). Fatigue interfered with enjoyment of life with mean scores of 3.3 (SD=3.1) and with enjoyment of life with reported mean scores of 3.3 (SD=3.1). Among the gender specific interference scores, fatigue interfered the most with levels of activity with a mean of 4.4 (SD=4.3) in men and a mean of 3.3 (SD=3.0) in women. Fatigue interfered least with ability to bathe and dress self with men reporting a mean of 1.5 (SD=3.0) and women reporting a mean of 1.0 (SD=1.3) (Table 5). There were no significant differences in scores between women and men.

Table 4

Means and Standard Deviations (SD) with Independent t-test Comparison of Severity and Frequency Items on the FSI Questionnaire

Fatigue in past week		mean	SD	t	p
Highest level	Overall	5.9	3.0		
	Male	6.4	3.1	1.212	.231
	Female	5.4	3.0		
Lowest level	Overall	2.1	1.9		
	Male	2.4	2.0	.981	.332
	Female	1.9	1.7		
Average level	Overall	4.0	2.5		
	Male	4.4	2.6	1.192	.239
	Female	3.6	2.3		
Level now	Overall	3.0	2.7		
	Male	3.6	3.1	1.430	.160
	Female	2.5	2.2		
How many days	Overall	4.7	2.5		
	Male	4.8	2.6	.279	.782
	Female	4.6	2.5		
How much of the day on average	Overall	4.5	3.1		
	Male	5.2	3.3	1.544	.130
	Female	3.8	2.7		

Table 5

Means and Standard Deviations (SD) with Independent t-test Comparison of Interference Items on the FSI Questionnaire

Fatigue in past week		Mean	SD	t	p
Rate interfered with level of activity	Overall	3.9	3.7		
	Male	4.4	4.3	1.107	.274
	Female	3.3	3.0		.275
Rate interfered with ability to bathe and dress self	Overall	1.2	2.3		
	Male	1.5	3.0	.862	.393
	Female	1.0	1.3		.395
Rate interfered with normal work activity	Overall	3.6	3.5		
	Male	3.8	3.9	.404	.688
	Female	3.4	3.1		.688
Rate interfered with ability to concentrate	Overall	2.7	3.1		
	Male	3.0	3.4	.675	.503
	Female	2.4	2.8		.503
Rate interfered with relations with other people	Overall	2.5	3.0		
	Male	3.0	3.4	1.122	.267
	Female	2.0	2.6		.268
Rate interfered with enjoyment of life	Overall	3.3	3.1		
	Male	3.9	3.6	1.313	.195
	Female	2.8	2.6		.196
Rate interfered with mood	Overall	3.0	3.2		
	Male	3.6	3.7	1.075	.288
	Female	2.6	2.5		.288

Short-Form-36 (SF-36)

Quality of life was measured utilizing the SF-36 health survey instrument. Overall physical functioning revealed a mean score of 54.9 (SD=29.7). The overall mean score for physical role limitations was 34.5 (SD=42.2) and vitality 35.1 (SD=24.2). Both were below the midpoint indicating lower states of health. The remaining mean scores were nearing or above the midpoint indicating average to better states of health (Table 6).

Again, no significant gender differences were noted in quality of life measures. Lower scores on this instrument represent a worse state of health and higher scores represent a better state of health. Overall, physical functioning

was the most affected of the eight domains measured by the SF-36. Men

reported mean scores of 48.6 (SD= 31.2), while women reported mean scores of

61.2 (SD=27.2). Of the eight scales, bodily pain was reported similarly among

this sample with a reported mean score of 69.5 (SD=31.1) in men and 69.9

(SD=26.0) in women (Table 6). Of note, women reported better states of health

than men, but this did not prove to be statistically significant upon analysis.

Table 6

Means and Standard Deviations (SD) with Independent t-test Comparison of Items on the SF-36

Questionnaire

Variable		Mean	SD	t	p
Physical Functioning	Overall	54.9	29.7		
	Male	48.6	31.2	-1.522	.135
	Female	61.2	27.2		
Role Limitations – Physical	Overall	34.5	42.2		
	Male	31.0	41.0	-.582	.563
	Female	38.0	44.0		
Role Limitations – Emotional	Overall	68.7	42.8		
	Male	62.7	45.5	-.991	.327
	Female	74.7	40.0		
Vitality	Overall	35.1	24.2		
	Male	30.8	23.9	-1.265	.212
	Female	39.4	24.2		
Mental Health	Overall	72.0	24.2		
	Male	68.0	29.8	-1.174	.246
	Female	76.0	16.5		
Social Functioning	Overall	64.0	29.2		
	Male	59.0	31.1	-1.217	.230
	Female	69.0	26.8		
Bodily Pain	Overall	69.7	28.4		
	Male	69.5	31.1	-.049	.961
	Female	69.9	26.0		
General Health	Overall	45.9	19.3		
	Male	43.7	18.2	-.815	.419
	Female	48.1	20.4		

Chart Audit Form

For each of the 50 subjects, physician and nursing documentation was

reviewed at baseline visit and at first visit after chemotherapy for documentation

of presence of fatigue and method utilized to assess and define fatigue. Physician documentation of fatigue was noted to occur at a rate of 33% and nurses at a rate of 21%. The two tools employed by practitioners to assist in screening for fatigue were the four-point verbal rating scale and the four-point numeric scale.

Discussion

Demographic Data

Data on the subjects was extracted from a much larger study currently being conducted in the ambulatory care clinics of a large, National Cancer Institute-designated comprehensive cancer center. The sample consisted of an equal number of middle-class, white women and men. All of the participants had advanced lung cancer and were receiving chemotherapy. Few of the subjects were receiving concurrent radiation therapy or biotherapy so the results are not reflective of more vigorous therapy. Also, few of the patients had received prior chemotherapy so the results are not generalized to those patients who have received other lines of therapy.

All of the subjects participating on the study had an ECOG PS of zero or one. An ECOG PS of zero indicates no symptoms and a one indicates minimal symptoms. The study prohibited patients with an ECOG performance status of greater than two from participating. Many patients with advanced stages of lung cancer and a Performance Status two are eligible for palliative chemotherapy and likely the results are not representative of fatigue levels and quality of life in this population. The sample was small, predominantly white and gathered from a

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single geographic area; thus, results may not be generalizable beyond this sample.

Fatigue Symptom Inventory (FSI)

Although the results of this study did not reveal a statistical significance in the severity, frequency, interference, or patterns of fatigue scores among the male and female participants, it did reveal some important findings. For the highest level of fatigue in the past week, men and women reported moderate levels of fatigue. Men and women reported fatigue on nearly 5 out of 7 days in the past week. Fatigue, in both genders, interfered mostly with activity levels.

Male participants scored the 14-item fatigue measures consistently higher than female participants. The rate that fatigue interfered with enjoyment of life in the past week item revealed a mean score of 3.9 (SD=3.6) for the male subjects versus 2.8 (SD=2.6) for the female subjects. The rate that fatigue interfered with relationships with other people and with mood in the past week showed mean scores of 3.0 (SD=3.4) and 3.6 (SD=3.7) for the male participants respectively, while the mean scores for the female participants were 2.0 (SD=2.6) and 2.6 (SD=2.5) respectively.

A limitation of this study was that fatigue was measured after the completion of a single cycle of chemotherapy. Fatigue tends to be cumulative over the course of multiple cycles of chemotherapy. The scores derived in this study are likely not reflective of the severity, frequency, interference and patterns of fatigue patients experience with receiving more than one cycle of chemotherapy. Also, a majority of the patients on the study were receiving

chemotherapy alone and for those receiving concurrent radiation therapy or biotherapy, fatigue may be amplified.

SF-36

Overall, the subjects reported average to better states of health on the items of this measurement tool. Physical role limitations and vitality scores were reported below midpoint and indicated perceived lesser states of health.

The study results did not confirm statistically significant gender differences in quality of life measures. Again, male participants scored all items of the SF-36 lower than female participants. Physical functioning appeared to affect health scores in men more so than women. Men and women reported similar states of health for the physical role limitations and bodily pain items. Both reported states of health below midpoint for physical role limitations and states of health above midpoint in relation to effect of bodily pain.

Fatigue assessment

As fatigue is the most prevalent and most distressing symptom reported by advanced lung cancer patients, the need for consistent assessment is imperative. There are well-established interventions to address the issue of fatigue in cancer patients. Interventions to impact or alleviate fatigue cannot be employed if fatigue is not assessed. Significant fatigue can lead to patients suffering in silence or ceasing therapy prematurely.

While assessment of fatigue may be routinely performed by practitioners during office visits, the documentation examined in this study does not reflect this practice. Physicians did document patients' reports of fatigue more often than

nurses; however, rates of documentation were still quite low. Both practitioners

utilized the four- point verbal rating scale more frequently than other methods of

fatigue assessment. Several nurses utilized the four-point numeric rating scale;

however, it should be noted that many of the subjects were on a concurrent

chemotherapy trial and data in this format was required to document toxicities. It

is unknown, since symptoms tend to occur in clusters, if other symptoms such as

pain or nausea and vomiting supersede the assessment and documentation of

fatigue in daily practice. The sample examined was small and all the subjects

were recruited from a single ambulatory clinic.

Implications for Nursing

Fatigue and quality of life (QOL) are critical concepts for nurses to seek to

understand. Although this study did not establish statistically significant gender

differences in fatigue and QOL, it did reveal that fatigue is a problem for

advanced lung cancer patients and that QOL is impacted. In an effort to better

support and treat these patients, nurses should be assessing for the presence of

fatigue and incorporating possible interventions into nursing plans of care. Also,

timely assessment of fatigue and subsequent intervention may assist patients in

complying with treatment plans and lessen the incidence of cessation of therapy

due to intolerable toxicity in the form of fatigue.

Provider assessment of fatigue was inconsistently and poorly documented

in this study. In order to develop interventions to assist advanced lung cancer

patients with fatigue and impact QOL, nurses must assess for the presence of

the symptom first. Barriers to assessment of fatigue must be addressed and

scales that assist in more consistent assessment and documentation of fatigue must be developed.

<div align="center">*Conclusions*</div>

No statistically significant gender differences were noted in the levels, severity, frequency or interference of fatigue in the sample utilized in this study. Also, no statistically significant gender differences were noted in quality of life measures. Although there were some trends toward differences in men and women with advanced lung cancer, no significant differences were found. A larger sample may reveal a statistical difference which would confer the need to be aware of this difference when applying interventions to address fatigue. As fatigue has been shown to be a prevalent and distressing symptom in advanced lung cancer patients, it is important that as many facets of this issue are explored and documented by practitioners. For the established interventions to assist in addressing fatigue and the many implications its presence has and to generally better serve these patients, assessment and subsequent documentation of fatigue levels must occur.

Recommendations for future research

Since the data from this study revealed that there was no difference in reported fatigue levels and quality of life levels between men and women, future studies should be conducted with larger sample sizes to determine if there exists a statistical significance. Future studies should also seek to accrue a more racially diverse sample. Expanding the exploration of practitioner assessment of fatigue is imperative and should occur in multiple settings to truly establish

pattern. Further studies as to the actual and perceived barriers to fatigue

assessment and documentation by practitioners are imperative.

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Appendices

Appendix A: Chart Audit Form

Subject Number	Date of Visit	Patient Screened for Presence and Severity of Fatigue?		Method or Tool Utilized to Screen?				
		Physician	Nurse	4 point verbal rating scale	5 point verbal rating scale	11 point numeric scale	4 point numeric scale	10cm visual analogue scale

ID   __ __ __

GENDER   **0** Male   **1** Female

HEIGHT __ __ __   inches

WEIGHT Pre-chemo weight: __ __ __ lbs.

GROUP   **1** UCO   **2** SM   **3** EX   **4** SMEX

DXDATE Date of initial diagnosis for cancer (physician approval date): __ __ / __ __ / __ __ __ __ (mm/dd/yy)

RCDATE Date of diagnosis of cancer recurrence requiring current chemo: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

CATYPE Cancer type __ __

1. Adrenal	16. Liver	31. Sarcoma, not osteosarcoma	
2. Bladder	17. Lung		
3. Bone (e.g., osteosarcoma)	18. Lymphoma (Hodgkins, NHL, Mycosis Fungoides)	32. Squamous Cell	
		33. Testicular	
4. Breast		34. Thyroid	
5. Brain	19. Melanoma	35. Unknown Primary	
6. Carcinoid (GI)	20. Merkle Cell		
7. Cervical	21. Mesothelioma	36. Uterine	
8. Colon	22. Multiple Myeloma	37. Vaginal/Vulvar	
9. Endometrial	23. Nasal & Sinus	88. Other:	
10. Esophageal	24. Pharyngeal		
11. Gastric (Stomach)	25. Neuroblastoma		
12. Kidney	26. Ovarian		
13. Layrnx	27. Pancreatic		
14. Leukemia (ALL, AML, CLL, CML)	28. Prostate		
	29. Rectal/Anal		
15. Lip & Oral cavity	30. Salivary		

CATYPE2 Does patient have a second cancer diagnosis?   If yes, enter code from list: __ __
                                                                                        If no, leave blank.

STAGE Stage at start of chemo: ___ **1** Stage I
                (Check one)   ___ **2** Stage II
                                                        ___ **3** Stage III
                                                        ___ **4** Stage IV
                                                        ___ **5** Limited Stage SCLC
                                                        ___ **6** Extensive Stage SCLC

ECOG0 Pre-Chemo ECOG Performance Status (check one):

___ **0** Fully active, able to carry on all pre-disease performance without restriction

___ **1** Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work

___ **2** Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours

___ **3** Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours

___ **4** Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair

<u>Surgery</u>

SURG1D Most recent surgery date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

SURG2D Previous surgery date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

SURG3D Previous surgery date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

<u>Radiation Therapy</u>

XRTC XRT while on study**:** No **0**   Yes **1**

   XRTCTX Number of XRT treatments while on study: __ __
   XRTCDS Total dose of XRT while on study: __ __ __ __
   XRTCSD Date of first Tx on study: __ __ / __ __ / __ __ __ __ (mm/dd/yy)
   XRTCED Date of last Tx on study: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

XRTP1 XRT prior to current chemo (most recent previous course):   No **0**   Yes **1**

   XRTP1TX Number of treatments during this course: __ __
   XRTP1DS Total dose of XRT during this course: __ __ __ __
   XRTP1SD Tx Start Date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)
   XRTP1ED Tx End Date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

XRTP2 XRT prior to current chemo (course before most recent previous course):   No **0**
Yes **1**

   XRTP2TX Number of treatments during this course: __ __
   XRTP2DS Total dose of XRT during this course: __ __ __ __
   XRTP2SD Tx Start Date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)
   XRTP2ED Tx End Date: __ __ / __ __ / __ __ __ __ (mm/dd/yy)

Appendix B: (Continued)

Concurrent Hormone Treatment

> **HORTX1** Hormone treatment while on study**:**   No **0**   Yes **1**

> **HORTXTY1** Type of hormone treatment: ___ **0** None
>
> ___ **1** Tamoxifen (Nolvadex)
>
> ___ **2** Megestrol (Megase)
>
> ___ **3** Leuprolide (Lupron)
>
> ___ **4** Gosarelin (Zoladex)
>
> ___ **5** Medroxyprogesterone (Provera)
>
> ___ **6** Triptorelin (Trelstar)
>
> ___ **7** Anastrozole (Armidex)
>
> ___ **8** Femara (Letrozole)

> **HORSD1** Date of first Tx while on study: __ __ / __ __ / __ __ __ __   (mm/dd/yy)
> **HORED1** Date of last Tx while on study: __ __ / __ __ / __ __ __ __   (mm/dd/yy)

> **HORTX2** Hormone treatment while on study**:**   No **0**   Yes **1**

Concurrent Biological Treatment

> **BIOTX** Biological treatment while on study**:**   No **0**   Yes **1**

> **BIOTXTY** Type of biological treatment: ___ **0** None
>
> ___ **1** Herceptin (Trastuzumab)
>
> ___ **2** BCG (Bacillus Calmete-Guérin)

> **BIOSD** Date of first Tx while on study: __ __ / __ __ / __ __ __ __   (mm/dd/yy)
> **BIOED** Date of last Tx while on study: __ __ / __ __ / __ __ __ __   (mm/dd/yy)

Previous Chemotherapy

PRVCHM Did patient receive chemo prior to the current chemo?No **0**   Yes **1**

PRVCHMX How many prior courses of chemo did patient receive? __ __

(a course refers to a uniform prescription of chemotherapeutic drugs administered over a series of cycles, usually 21 day cycles)
CHM1 Chemo prior to current chemo (most recent previous course):   No **0**   Yes **1**

GBI

1. Today's date: / /   (MM/DD/YYYY)

2. Birth date: / /   (MM/DD/YYYY)

3a. Ethnic group (check one):
Hispanic/Spanish/Latino
Not Hispanic/Spanish/Latino

3b. Racial Background (check one):
American Indian or Alaskan Native
Asian
Black or African American
More than one race (specify):
Native Hawaiian/Pacific Islander
White

4. Marital status (check one):
Never married
Currently married
Separated
Divorced
Widowed

5a. Current living arrangement (check one box):
Live alone
Live with spouse/partner
Live with spouse/partner and children
Live with children (no spouse/partner)
Live with roommate who is not partner
Live with parents
Other (specify):

5b. Number of children living at home (enter 0 if none):

6. How long in current living arrangement (check one):
Less than 1 month
One to 6 months
Seven months to less than 2 years
Two to 5 years
More than 5 years

7. Level of school completed (check one):
Less than 7th grade
Junior High School (7th, 8th, & 9th grade)
Partial High School (10th or 11th grade)
High School graduate
Partial college or specialized training
College or university graduate
Graduate professional training (graduate degree)

8. Current employment situation (check the one box that applies the most):
A. WORKING
       Full time at job
       Part time at job
B. ON LEAVE
       On leave with pay
       On leave without pay
C. NOT
EMPLOYED
       Disabled
       Seeking work
       Retired
       Homemaker
       Student

9. Which category best describes your usual occupation? If you are not currently employed, which category best describes your LAST job? (check one):
Professional (e.g., teachers/professors, nurses, lawyers, physicians, & engineers)
Manager/Administrator (e.g., sales managers)
Clerical (e.g., secretaries, clerks, or mail carriers)
Sales (e.g., sales persons, agents, or brokers)
Service (e.g., police, cooks, waiters, or hairdressers)
Skilled Crafts, Repairer (e.g., carpenters)
Equipment or Vehicle Operator (e.g., truck drivers)
Laborer (e.g., maintenance or factory workers)
Farmer (e.g., owners, managers, operators, or tenants)
Member of the military
Homemaker (with no job outside the home)
Other (please describe)

10. Which category best describes your spouse's usual occupation? If your spouse is not currently employed, which category best describes his/her LAST job? (check one):
Do not have a spouse
Professional (e.g., teachers/professors, nurses, lawyers, physicians, & engineers)
Manager/Administrator (e.g., sales managers)
Clerical (e.g., secretaries, clerks, or mail carriers)
Sales (e.g., sales persons, agents, or brokers)
Service (e.g., police, cooks, waiters, or hairdressers)
Skilled Crafts, Repairer (e.g., carpenters)
Equipment or Vehicle Operator (e.g., truck drivers)
Laborer (e.g., maintenance or factory workers)
Farmer (e.g., owners, managers, operators, or tenants)
Member of the military
Homemaker (with no job outside the home)
Other (please describe)

11. What is **your** approximate annual gross income? (check one)
(Remember all information you provide will remain completely confidential)
Less than $10,000
$10,000 - $19,999
$20,000 - $39,999
$40,000 - $59,999
$60,000 - $100,000
Greater than $100,000
Prefer not to answer

12. Approximate annual gross income for your **household**: (check one box)
(Remember all information you provide will remain completely confidential)
Less than $10,000
$10,000 - $19,999
$20,000 - $39,999
$40,000 - $59,999
$60,000 - $100,000
Greater than $100,000
Prefer not to answer

FSI
For each of the following, check one box next to the number that best indicates how that item
applies to you.
1. Rate your level of fatigue on the day you felt **most** fatigued during the past week:

0	1	2	3	4	5	6	7	8	9	10

Not at all   **As fatigued**
Fatigued   **as I could be**

2. Rate your level of fatigue on the day you felt **least** fatigued during the past week:

0	1	2	3	4	5	6	7	8	9	10

Not at all   **As fatigued**
Fatigued   **as I could be**

3. Rate your level of fatigue on the **average** during the past week:

0	1	2	3	4	5	6	7	8	9	10

Not at all   **As fatigued**
Fatigued   **as I could be**

4. Rate your level of fatigue **right now**:

0	1	2	3	4	5	6	7	8	9	10

Not at all   **As fatigued**
Fatigued   **as I could be**

5. Rate how much, in the past week, fatigue interfered with your **general level of activity**:

0	1	2	3	4	5	6	7	8	9	10

No   **Extreme**
Interference   **interference**

6. Rate how much, in the past week, fatigue interfered with your **ability to bathe and dress yourself**:

0	1	2	3	4	5	6	7	8	9	10

No   **Extreme**
Interference   **interference**

7. Rate how much, in the past week, fatigue interfered with your **normal work activity (includes both work outside the home and housework)**:

0	1	2	3	4	5	6	7	8	9	10

No   **Extreme**
Interference   **interference**

8. Rate how much, in the past week, fatigue interfered with your **ability to concentrate**:

0	1	2	3	4	5	6	7	8	9	10
No Interference										**Extreme interference**

9. Rate how much, in the past week, fatigue interfered with your **relations with other people**:

0	1	2	3	4	5	6	7	8	9	10
No Interference										**Extreme interference**

10. Rate how much, in the past week, fatigue interfered with your **enjoyment of life**:

0	1	2	3	4	5	6	7	8	9	10
No Interference										**Extreme interference**

11. Rate how much, in the past week, fatigue interfered with your **mood:**

0	1	2	3	4	5	6	7	8	9	10
No Interference										**Extreme interference**

12. Indicate **how many days**, in the past week, you felt fatigued for any part of the day:

0	1	2	3	4	5	6	7
Days							**Days**

13. Rate **how much of the day,** on average, you felt fatigued in the past week:

0	1	2	3	4	5	6	7	8	9	10
None of the day										**The entire day**

14. Indicate which of the following best describes the **daily pattern** of your fatigue in the past week:

0	1	2	3	4
Not at all fatigued	**Worse in the morning**	**Worse in the afternoon**	**Worse in the evening**	**No consistent daily pattern of fatigue**

1. In general, would you say your health is
Excellent   Very good   Good   Fair   Poor

2. Compared to one week ago, how would you rate your health in general now?

Much better now than one week ago.............
Somewhat better now than one week ago....
About the same...
Somewhat worse now than one week ago.....
Much worse now than one week ago.............

3. The following items are about activities you might do during a typical day. *Does your health now limit you* in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports...			
b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling or playing golf...			
c. Lifting or carrying groceries....................................			
d. Climbing *several* flights of stairs.............................			
e. Climbing *one* flight of stairs...................................			
f. Bending, kneeling or stooping.................................			
g. Walking *more than a mile*.......................................			
h. Walking *several* blocks..			
i. Walking *one* block..			
j. Bathing or dressing yourself....................................			

4. During the *past week*, have you had any of the following problems with your work or other regular dailyactivities *as a result of your physical health?*

	Yes	**No**
a. Cut down the *amount of time* you spent on work or other activities...		
b. *Accomplished less* than you would like..		
c. Were limited in the *kind* of work or other activities..........................		
d. Had *difficulty* performing the work or other activities (for example it took extra effort)...		

5. During the *past week*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

Yes   No

a. Cut down the *amount of time* you spent
on work or other activities...
b. *Accomplished less* than you would like..
c. Didn't do work or other activities as *carefully* as usual.....................

6. During the *past week*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all.........................
Slightly............................
Moderately......................
Quite a bit.......................
Extremely........................

7. How much *bodily pain* have you had during the past week?

None......................
Very mild..............
Mild.....................
Moderate...............
Severe...................
Very severe.............

8. During the *past week*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all.........................
A little bit.........................
Moderately......................
Quite a bit.......................
Extremely........................

9. These questions are about how you feel and how things have been with you *during the past week*. For each question, please give the one answer that comes closest to the way you have been feeling.

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time

How much of the time during the past week:

a. Did you feel full of pep?.............
b. Have you been a nervous person?.....................................
c. Have you felt so down in the dumps that nothing could cheer you up?..
d. Have you felt calm and peaceful?..................................
e. Did you have a lot of energy?....
f. Have you felt downhearted and blue?..
g. Did you feel worn out?...............
h. Have you been a happy person?
i. Did you feel tired?.......................

10. During the *past week*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time...............
Most of the time...........
Some of the time..........
A little of the time.......
None of the time............

11. Please choose the answer that best describes how **TRUE** or **FALSE** each of the following statements *is for you.*

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False

a. I seem to get sick a little easier than other people..........................
b. I am as healthy as anybody I know...
c. I expect my health to get worse....
d. My health is excellent...................

12. How much *nausea* have you had during the *past week*? (Check one)
> **None......................**
> **Very mild..............**
> **Mild.....................**
> **Moderate...............**
> **Severe...................**
> **Very severe..........**

13. During the *past week*, how much did *nausea* interfere with your normal work (including both work outside the home and housework)? (Check one)

> **Not at all.................**
> **A little bit................**
> **Moderately.............**
> **Quite a bit..............**
> **Extremely..............**