

QUALITY OF LIFE IN PATIENTS RECEIVING
CURATIVE RADIATION THERAPY FOR
NON-SMALL CELL LUNG CANCER

A DISSERTATION
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY
IN THE GRADUATE SCHOOL OF THE
TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NURSING

BY
LAURI D. JOHN, B.S., B.S.N., M.S.N

DENTON, TEXAS

May 1997

TEXAS WOMAN'S UNIVERSITY
DENTON, TEXAS

March 4, 1997
Date

To the Associate Vice President for Research and Dean of the
Graduate School:

I am submitting herewith a dissertation written by Lauri D.
John entitled "Quality of Life in Patients Receiving
Curative Radiation Therapy for Non-Small Cell Lung Cancer."
I have examined the final copy of this dissertation for form
and content and recommend that it be accepted in partial
fulfillment of the requirements for the degree of Doctor of
Philosophy, with a major in Nursing.

Anne Young
Anne Young, Major Professor

We have read this dissertation
and recommend its acceptance:

Sandra K. Hammerman

K. Lynn Wreck

Accepted.

Leslie M Thompson
Associate Vice President for
Research and Dean of the
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ACKNOWLEDGMENTS

I would like to express my sincere gratitude to my dissertation committee members for their guidance and support which led to the completion of this research investigation. Special thanks to my committee chair, Dr. Anne Young, for her suggestions and encouragement throughout the dissertation process. To Dr. Sandy Hanneman, special appreciation is due for her expert guidance in the research process. To Dr. Lynn Wieck, much gratitude is due for her most welcome editorial advice and boundless enthusiasm.

I would also like to thank the lung cancer patients at M.D. Anderson Cancer Center who participated in this study. Special recognition is also due to Dr. Randi Schea for his encouragement and for imparting to me his knowledge and expertise in radiation oncology.

To all my friends and colleagues, thank-you for supporting me when I needed it most. Special thanks to Rosemary, Annabelle, Kristin, and Theresa.

To my parents, much love and many many thanks for your love, support, and patience throughout all of my endeavors.

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Lauri D. John

May 1997

Despite increased interest in the study of quality of life (QOL) in recent years, there has been little research in lung cancer patients. Combined-modality lung cancer treatment regimens have had an impact on overall survival duration; however the impact of these increasingly toxic treatments on QOL has received scant attention. The purpose of this study was to determine if perceptions of QOL change over time in patients with non-small cell lung cancer (NSCLC) receiving curative radiation therapy (XRT) alone or in combination with other treatment modalities.

A descriptive, longitudinal design with repeated measures was used to study perceptions of QOL in NSCLC patients receiving curative XRT. A nonprobability, consecutive sampling technique was used to select 23 NSCLC patients receiving XRT in the radiotherapy clinic of a comprehensive cancer treatment center located in Southeast Texas. The Functional Assessment of Cancer Therapy-Lung (FACT-L) (Cella, 1994), a 37-item Likert-type questionnaire that measures QOL in lung cancer patients, was used to

assess QOL prior to subjects' beginning XRT, during the fourth week of treatment, and one month and four months after XRT completion. A data sheet was used to record descriptive information.

The research question of the study, do perceptions of QOL change over time in NSCLC patients receiving curative XRT, was examined using a multivariate approach to analysis of variance for repeated measures with five planned comparisons. QOL was significantly lower during XRT than it was before XRT ($p = .006$) and was significantly greater one month after XRT than it was before XRT ($p = .01$) or during XRT ($p < .0005$). QOL four months after XRT was not significantly different from the pretreatment level ($p = .15$).

These findings suggest that QOL does change in NSCLC patients receiving curative XRT. Although QOL declines significantly during XRT, it improves following XRT to a level higher than prior to treatment and then returns to the pre-treatment level. It may be concluded that additional nursing interventions need to be developed to support QOL in NSCLC patients while they are receiving curative XRT.

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CHAPTER 1

INTRODUCTION

Lung cancer has been the leading cause of cancer deaths in men since the 1950s and in women since 1987 (American Cancer Society, 1996). It is estimated that in 1996, 177,000 people will be diagnosed with lung cancer in the United States and that 158,700 having the diagnosis of lung cancer will die from their disease. Approximately 85% of lung cancers are classified as non-small cell lung cancer (NSCLC) with the remainder classified as small cell lung cancer (SCLC) (Martini, 1993).

Patients who receive no treatment for their lung cancer typically die within one year of diagnosis and have a median survival of less than six months (Martini, 1993). Surgery, radiation therapy (XRT), and chemotherapy, alone or in combination, are the treatment modalities employed for lung cancers. Although improved NSCLC patient survival has been demonstrated through use of high-dose radiation therapy (Cox et al., 1990; Perez et al., 1980) and use of combined-modality therapy (Dillman et al., 1990; Sause et al., 1992), increased incidence of toxicities has also been observed.

The overall impact of these treatments on patients' lives has rarely been reported.

Quality of life (QOL) is a concept that has received increased attention from health care professionals in recent years. Although treatment effectiveness has traditionally been measured in terms of curing disease and prolonging life, improvement of patients' QOL has gained in importance as an outcome measure in the treatment of many health problems. Despite increased interest in the study of QOL in recent years, there has been little research in the lung cancer patient population. This research has mostly addressed the impact of chemotherapy in treatment of SCLC and only rarely has included NSCLC patients. The impact of treatment with XRT on the quality of lung cancer patients' lives has thus far received scant attention in the literature.

Although use of the term QOL has increased in frequency, no consensus has been reached regarding its definition or measurement. Based on review of the literature, several common attributes of QOL have been identified: a) life evaluation using subjective and objective measures and b) assessment of satisfaction and well-being in the physiological, psychological, and sociological domains of life.

Wellisch (1984) discussed QOL as a response to a flow of events rather than merely an assessment of the person's status at a single point in time. Perceptions of QOL, therefore, change in response to life events such as treatment for lung cancer. Although research related to QOL should be sensitive to the changes that occur in perceptions of QOL over time, prospective, longitudinal studies have rarely been undertaken in the study of QOL. Future studies of the impact of XRT (alone or in combination with other treatment modalities) on QOL in NSCLC patients should therefore address the dynamic nature of QOL perceptions.

Problem of Study

The purpose of this study was to determine if perceptions of quality of life change in NSCLC patients in response to radiation therapy with curative intent.

Rationale for Study

As the second leading cause of death in the United States, cancer has long been recognized as a major health problem (American Cancer Society, 1996). Lung cancer is the leading cause of cancer deaths.

Treatment and prognosis for those diagnosed with lung cancer are influenced by histologic classification and by the extent of spread (stage) of the disease. In the

histologic classification of lung cancer, the primary distinction is between small cell lung carcinoma (SCLC), which includes approximately 15% of all lung cancers, and non-small cell lung carcinoma (NSCLC), which includes the remainder. SCLC usually presents with distant metastasis of disease at the time of diagnosis; NSCLCs, particularly squamous cell carcinoma, have a slightly lesser tendency to present with widespread metastasis (Komaki & Cox, 1993).

Survival expectations and results of research regarding the treatment of lung cancer are communicated in terms of the stage of the cancer at the time of its diagnosis. The staging system incorporates classification of the primary tumor, extent of lymph node involvement, and presence of distant metastasis (American Joint Committee on Cancer [AJCC], 1992). The projected survival time of lung cancer patients is less in those with more advanced stages of the disease at the time of diagnosis.

Surgical resection is considered the most effective treatment of NSCLC and has provided up to 40% to 60% five-year survival with earlier stages of disease (Ginsberg, 1989). Unfortunately, only about 30% of NSCLCs are completely resectable. Postoperative XRT has been shown to increase five-year survival in NSCLC patients from 16% to 31% (Green, Kurohara, George, and Crews, 1975) and from 0%

to 26% (Kirsh & Sloan, 1982) compared with surgical resection alone.

In patients with unresectable NSCLC, higher doses of XRT have improved local control to 67% compared with 46% with lower doses (Perez et al., 1980). Cox et al. (1990) found a median survival of 13 months and a two-year survival rate of 29% in patients who received higher XRT doses compared with a median survival of nine months and two-year survival rate of 10% in those receiving lower doses. Increased frequencies of more severe early and late toxicities were found in those receiving the higher doses.

Recent clinical trials in which chemotherapy has been administered in combination with XRT have improved median survival to 13.9 months compared with 9.7 months in NSCLC patients receiving XRT alone (Dillman et al., 1990; Sause et al., 1992). These treatment regimens were also associated with increased toxicities.

Although improved NSCLC patient survival has been demonstrated through use of high-dose XRT and use of combined-modality therapy, the effect of these treatments on the patients' lives, other than occasional mention of increased incidence of toxicities, has not been consistently reported. Despite increased interest in the study of QOL in recent years, there have been no reported studies of the

impact on QOL of NSCLC treatment with XRT alone or in combination with other treatment modalities. A study of the changes in perceptions of QOL in these NSCLC patients may be valuable in assisting nurses in assessment of level of QOL. Subsequently, interventions may be developed to facilitate patient adaptation to treatment and achievement of the most satisfactory level of QOL possible (optimum QOL) given the diagnosis of lung cancer.

Conceptual Framework

Those persons undergoing treatment for lung cancer are confronted by many stressors that affect their perceptions of QOL. The conceptual framework utilized in this study was the Roy Adaptation Model (Roy, 1980; Roy & Andrews, 1991). A brief description of the concepts and linkages of the model is presented followed by application to this study of QOL and a proposition relating the concepts that will be studied.

According to Roy (1980), the model drew heavily from Helson's work on adaptation and von Bertalanffy's work on systems theory. Roy conceptualizes person as a biopsychosocial being who constantly interacts with a changing environment. This person is an adaptive system who uses innate and acquired coping mechanisms to deal with

stressors encountered in the environment. These coping mechanisms are divided into two main subsystems: regulator and cognator. The regulator subsystem controls internal processes in response to physiologic needs and includes neural, endocrine, and chemical pathways. The cognator subsystem controls internal processes related to higher brain function and includes cognitive and emotive pathways. Regulator and cognator activities are manifested through behavior in four adaptive modes: physiologic function, self-concept, role function, and interdependence. The person's response to stimuli may be either adaptive or ineffective and may be assessed to determine level of adaptation. The response also provides feedback that becomes an additional stimulus for change or maintenance of the coping mechanisms and adaptive modes (see Figure 1).

The environment is conceptualized as all internal and external stimuli that affect adaptation (Roy & Andrews, 1991). The person attempts to respond adaptively to stimuli from the constantly changing environment. The combined effect of three types of stimuli determine the person's adaptation level. Focal stimuli are those that are immediately confronting the person. Contextual stimuli are the background environmental factors present in the situation that contribute to the effect of the focal

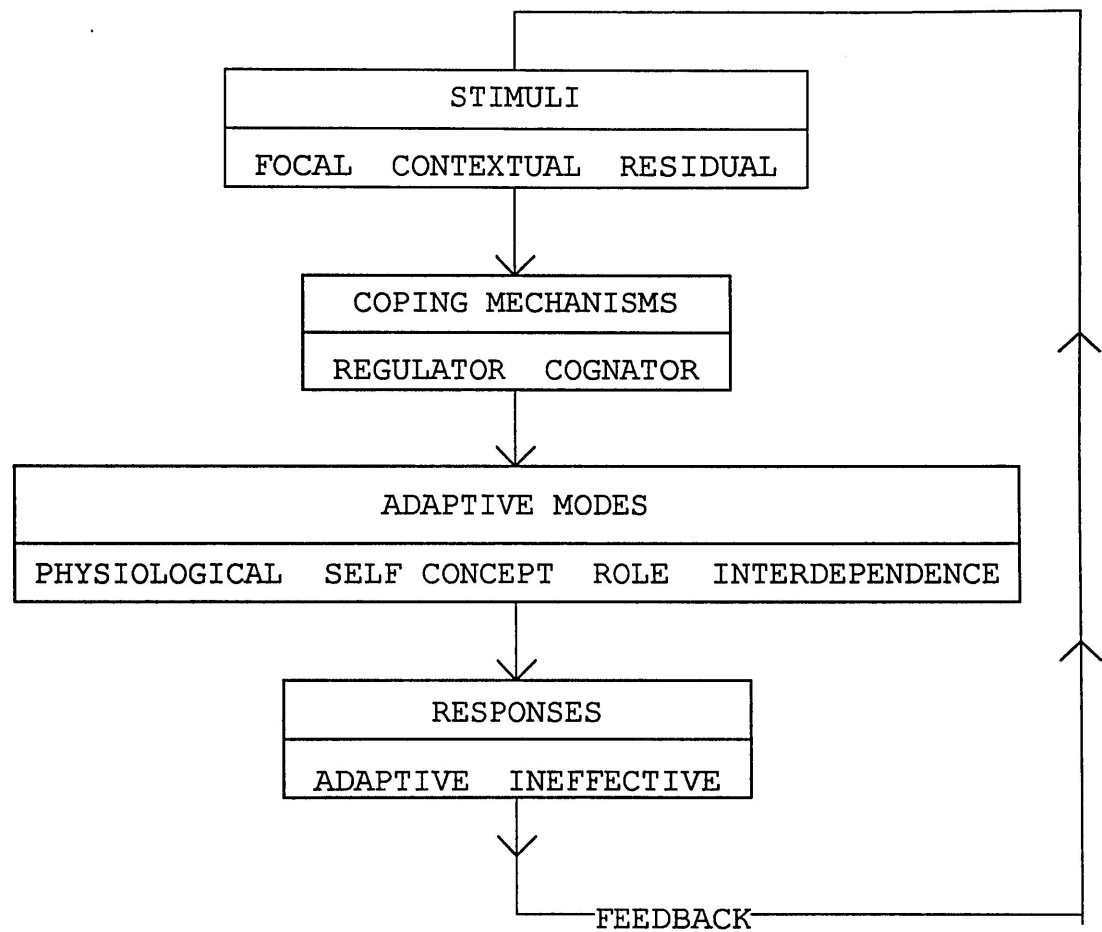


Figure 1. Schematic interpretation of the Roy Adaptation Model (Roy & Andrews, 1991).

stimuli. Residual stimuli are those that have an effect on the situation but are indeterminate. Adaptive responses are activated when incoming stimuli are disparate with the person's current level of adaptation.

In the Roy Adaptation Model, health is equated with integration and wholeness of the person, and lack of health

is equated with lack of integration (Roy & Andrews, 1991). Adaptive responses promote integrity and wholeness; therefore, health may be viewed as a reflection of the person's adaptation. Ineffective or maladaptive responses interfere with the person's ability to adapt and achieve health.

The goal of nursing in Roy's model is to promote adaptation in the four adaptive modes, thus assisting the person to achieve health, quality of life, and death with dignity (Roy & Andrews, 1991). Nursing activities include assessment of coping mechanisms, adaptive responses, and stimuli; manipulation of stimuli that influence adaptation; and promotion of adaptive responses.

In the framework of the model, the person with lung cancer often enters the health care system in response to symptoms, such as cough, hemoptysis, or shortness of breath, that are focal stimuli. Depending on the severity of the symptoms, they may become contextual stimuli when the person is confronted by the new focal stimulus of the lung cancer diagnosis. When the person begins treatment with XRT alone or in combination with other modalities, the diagnosis becomes a contextual stimulus and the treatment becomes the new focal stimulus. Other contextual stimuli include gender, age, nutritional status, pulmonary function, tobacco

and alcohol use, marital status, transportation, living arrangements, occupation, and financial status. Residual stimuli include values, beliefs, and perceptions of and expectations regarding QOL which are the result of feedback from prior cognator subsystem coping mechanism activity manifested through the adaptive modes.

These changing stimuli interact and influence adaptive ability of the person undergoing treatment for lung cancer. If the coping responses are effective, successful adaptation, e.g., optimum QOL, will be the output that provides feedback and becomes a residual stimulus for the person. If new stimuli are encountered, such as side effects from treatment, available coping responses of the regulator and cognator subsystems may be insufficient. Insufficient coping responses will result in output of ineffective adaptive response, e.g., suboptimum QOL, that will provide feedback and become an additional focal stimulus for the person. This feedback will result in reactivation of the coping mechanisms and adaptive modes to attempt to change the output to an adaptive response with optimum QOL.

Adaptive responses may be promoted and perception of QOL improved through nursing intervention. Education of the patient regarding clinic and hospital routines, expected

side effects and outcomes of treatment, and strategies to decrease the severity of side effects may promote adaptive responses. The output will be adaptation and perception of optimum QOL.

Based on Roy's conceptual framework, one proposition was derived that describes the relationships between the concepts of this study. It was proposed that the focal stimulus of XRT influences the adaptive ability of the person with NSCLC and results in alterations in adaptation level (perceptions of level of QOL).

Assumptions

The following assumptions from the Roy Adaptation Model (Roy, 1980) were applied to the present study of QOL:

1. The person (e.g., NSCLC patient) uses innate and acquired coping mechanisms in response to interaction with a focal stimulus (e.g., XRT alone or in combination with other treatments) from a changing environment.
2. Adaptation (e.g., perception of an optimal QOL) is a function of the person's current adaptation level, the focal stimulus encountered (e.g., XRT alone or in combination with other treatments), and the person's available coping mechanisms.

Research Question

The following research question was examined in this study:

1. Do perceptions of QOL change over time in NSCLC patients receiving curative radiation therapy?

Definitions of Terms

The following terms were theoretically and operationally defined for the purpose of this study:

Non-small cell lung carcinoma (NSCLC) patients were theoretically defined as biopsychosocial beings who must adapt to the contextual stimulus of NSCLC and the focal stimulus of curative radiation therapy alone or in combination with other treatment modalities (Roy, 1980). They were operationally defined as individuals who have been diagnosed with a primary malignant neoplasm of the lung that has been histologically classified as a NSCLC for which they will be treated with curative radiation therapy.

Curative radiation therapy was theoretically defined as a focal stimulus to which the person must respond (Roy, 1980). Operationally, it was defined as external beam radiation therapy (XRT) delivered to the primary lung tumor with curative intent using standard or investigational doses

and/or fractions of XRT alone or in combination with other treatment modalities.

Quality of life (QOL) was theoretically defined as the person's perception of level of satisfaction with life based on assessment of the interacting physiologic, self-concept, role function, and interdependence adaptive modes in response to focal, contextual, and residual stimuli (Roy, 1980). For the purposes of this study, QOL was operationally defined as the score on the Functional Assessment of Cancer Therapy-Lung (FACT) (Cella et al., 1993).

Limitations

Limitations of this study included the following:

1. Response bias arising from patient awareness of participation in the study may have affected validity of the results.
2. The results of this study should not be generalized beyond the sample studied because random sample selection was not utilized.

Summary

Lung cancer is a devastating and often fatal disease. Advances in the treatment of lung cancer have resulted in increased survival, but they have been accompanied by

increased toxicity. Although treatment effectiveness has traditionally focused on prolonging life, increased attention is now being focused on the quality of that life. Using the conceptual framework of the Roy Adaptation Model, this study examined the QOL of NSCLC patients receiving treatment with curative XRT alone or in combination with other treatment modalities. The purpose of the study was to determine if changes occur over time in NSCLC patients' perceptions of QOL in response to XRT with curative intent.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this review was to examine the literature related to treatment of non-small cell lung cancer (NSCLC) and to quality of life (QOL). The review of QOL literature was organized according to the following sub-topics: history and conceptual issues, research related to the general cancer patient population, and research related to the lung cancer patient population.

Treatment of Lung Cancer

Non-small cell lung cancer (NSCLC) includes adenocarcinoma, which accounts for 50% of all lung cancers, squamous cell carcinoma (SCCA), which accounts for 33%, and large cell carcinoma, which accounts for less than five percent (Martini, 1993). Small cell lung cancer (SCLC), which is the classification for 15% of all lung cancers, usually presents with distant metastasis of disease at the time of diagnosis; NSCLCs, particularly SCCA, have a lesser tendency to present with widespread metastasis (Komaki & Cox, 1993).

Survival expectations and results of research regarding the treatment of lung cancer are communicated in terms of

the stage of the cancer at the time of its diagnosis. The staging system incorporates classification of the primary tumor, extent of lymph node involvement, and presence of distant metastasis (American Joint Committee on Cancer [AJCC], 1992). Groupings of these classifications are combined to form the five stages of lung cancer (AJCC, 1992): I, II, IIIa, IIIb, and IV. Stage of disease at the time of diagnosis is inversely related to patient prognosis (\bar{r} not reported, $p < .001$) (Mountain, 1988).

Patients who receive no treatment for their lung cancer typically die within one year of diagnosis and have a median survival of less than six months (Martini, 1993). Surgery, radiotherapy (XRT), and chemotherapy are the treatment modalities employed for lung cancers.

Surgical resection is considered most effective in curative treatment of Stage I NSCLC, providing a 40 to 60% five-year survival (Ginsberg, 1989). Patients with Stage I NSCLC that is potentially resectable but who are medically inoperable or refuse surgery have been treated with curative XRT (Sandler, Curran, & Turrisi, 1989). The three-year disease-specific survival rate in the entire group of patients was 22%, and the median survival was 20 months. Size of the tumor at time of diagnosis was correlated with survival; patients with tumors three centimeters or smaller

had a three-year disease-specific survival rate of 34% compared with 0% in those with tumors larger than six centimeters. Impact of treatment on patients' lives was not reported.

Postoperative XRT has been shown to increase overall survival in NSCLC patients with limited nodal disease. According to a study by Green, Kurohara, George, and Crews (1975), five-year survival in patients with Stage I, II, or IIIa NSCLC was 31% in those who received postoperative XRT compared with 16% in those who were treated with surgery alone; differences in survival rates were also related to presence or absence of lymph node involvement. Similar results were reported by Kirsh and Sloan (1982) and by the Lung Cancer Study Group (LCSG) (Weisenburger, Gail, & LCSG, 1986). Impact of treatment on patients' lives was not reported in these studies.

In patients with unresectable NSCLC, administration of higher doses of XRT, compared with standard doses, has resulted in improved local control which has led to increased overall survival. In a study conducted by the Radiation Therapy Oncology Group comparing four different XRT treatment regimens (Perez et al., 1980, 1987), Stage IIIa and IIIb NSCLC patients who received higher XRT doses in continuous courses had local recurrence rates of 45% and

33%, respectively, compared with 51% and 64% in patients receiving lower doses in a split course or a continuous course. The three-year survival rate in patients who received higher XRT doses and did not experience local recurrence was 22% compared with 10% for those who experienced local recurrence; however, the five-year survival was the same for all patients (6%). Impact of treatment on patients' lives was not reported. Improved two-year and median survival statistics in those receiving higher XRT doses were also reported by Cox et al. (1990); however, patients receiving higher XRT doses experienced increased frequencies of more severe early and late toxicities.

Recent clinical trials in which chemotherapy has been administered in combination with XRT have produced improved survival for NSCLC patients. In Stage III NSCLC patients (Dillman et al., 1990), administration of induction chemotherapy prior to XRT improved median survival to 13.8 months compared with 9.7 months in patients receiving XRT alone. Rates of one, two and three-year survival were improved to 55%, 26%, and 23% compared with 40%, 13%, and 11%. Increased incidence of serious side effects were reported for those receiving induction chemotherapy before XRT. Additional studies in progress by the Radiation

Therapy Oncology Group have yielded similar preliminary results (Sause et al., 1992, 1995).

Although improved NSCLC patient survival has been demonstrated through use of high-dose XRT and use of combined-modality therapy, these regimens have been accompanied by more severe early and late toxicities. The effect of these treatments on the patients' lives, other than occasional mention of increased incidence of toxicities, has not been reported in the literature.

Quality of Life

History and Conceptual Issues

Spitzer (1987) discussed the evolution of use of the term QOL to describe human health and welfare. He linked its origin to the 1947 World Health Organization definition which equated health with physical, mental, and social well-being rather than freedom from disability and disease. What followed were attempts by researchers of many disciplines to develop global measures of health and a gradual shift from use of the terms functional status and health status to use of the term QOL. Based on his extensive review of the literature, Spitzer (1987) concluded that QOL includes the domains of physical function, social function, emotional or

mental status, burden of symptoms, and perception or sense of well-being. A review of the development of the concept and definition of QOL was also conducted by Fallowfield (1990) with similar results.

Schipper, Clinch, and Powell (1990) identified five concepts related to QOL. The first, the psychological concept, emphasized patient perceptions of the disease process. Second, the time trade-off or utility concept dealt with the decisions (trade-offs) that patients make between quality and quantity of life. The community-centered concept organized health status and QOL variables according to their impact on the community. The concept of reintegration to normal living concerned resumption of activities following an incapacitating illness or injury. Finally, the gap concept addressed the disparity between the patient's expectations and achievements.

Based on their review of the conceptual elements of QOL, Schipper et al. (1990) chose to define QOL as "the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient" (p. 16). Physical and occupational function, psychologic state, social interaction, and somatic sensation were identified as domains contributing to the functional effect. Although Schipper et al. did not delineate the role of the utility

and gap concepts in the QOL definition, these concepts might be incorporated in the domain of the psychologic state. Similar multidimensional conceptualizations of QOL were also developed through studies by Andrew and Withey (1976); Campbell, Converse, and Rogers (1976); and Flanagan (1978, 1982).

Wellisch (1984) discussed the concept that QOL is a response to a flow of events rather than merely an assessment of the person's status at a single point in time. Perceptions of QOL, therefore, change in response to life events such as treatment for lung cancer. Although research related to QOL should be sensitive to the changes that occur in perceptions of QOL over time, prospective, longitudinal studies have rarely been undertaken in the study of QOL.

Bowling (1991) described the concept of QOL based on her review of the literature. She concluded that QOL represents reactions of the individual to physical, mental, and social stressors on daily living that influence achievement of personal life satisfaction. She stated that it includes perceptions of well-being, satisfaction, and self-esteem in addition to physical well-being.

Kleinpell (1991) used concept analysis methods to clarify the concept of QOL. Based on an extensive literature review, she identified the following terms that

were frequently associated with the concept: life satisfaction, well-being, worth of life, value of life, and self-esteem. She stated that most definitions for QOL include "perceptions of well-being, satisfaction of needs, the ability to achieve security and self-esteem and to fulfill personal goals, and contentment or satisfaction with life" (p. 224). Kleinpell (1991) also identified inconsistencies between different definitions of QOL. Some definitions subscribe to the belief that QOL is a subjective experience (attitudes, well-being, perceptions) that can only be evaluated by the person experiencing it, but some view it as objective events (income, housing, physical function) that can be evaluated by an outside observer.

The defining attributes of QOL in cancer patients with pain were also studied by Padilla, Ferrell, Grant, and Rhiner (1990). Forty-one subjects were asked to respond to questions about the meaning of QOL, factors contributing to good or bad QOL, and the influence of pain on QOL. The investigators developed a conceptual model based on their findings which was later adapted for use in a study of the impact of bone marrow transplant on QOL (Ferrell et al., 1992). The domains identified for QOL were physical well-being and symptoms, psychological well-being, social well-being, and spiritual well-being.

The term QOL was not used as a key word in Medline, a computer-assisted search program for medical literature, until after 1975 (Spitzer, 1987). In a search of the literature from the period between 1975 and 1979, Najman and Levine (1981) found 23 papers investigating the impact of medical care on QOL. Hollandsworth (1988) found 344 papers pertaining to QOL in a Medline search of literature from the period between 1980 and 1984; of the 344 papers, 69 (20%) reported data-based studies of the impact of medical treatment on QOL. A current search of the literature from the period between 1984 and 1995 by this investigator using Medline yielded more than 3900 citations in which QOL was the major focus. Many of the citations concern the definition and measurement of QOL and its importance as an outcome measure, and few report results of clinical studies that include QOL as an outcome measure.

Quality of Life in Cancer

Hollandsworth (1988) found that 28 (41%) of the data-based studies of the impact of medical treatment on QOL cited between 1980 and 1984 dealt with various treatments for cancer. This investigator found that of the 3900 literature citations between 1984 and 1995 in which QOL was the major focus, 867 (22%) were related to cancer.

Danoff, Kramer, Irwin, and Gottlieb (1983) conducted a study of QOL in cancer patients who had received curative XRT and were alive and without evidence of disease at least three years after initial treatment. Of the 399 patients interviewed, most had diagnoses of breast ($\underline{n} = 134$, 33.6%), gynecologic ($\underline{n} = 93$, 23.3%), and head and neck ($\underline{n} = 69$, 17.8%) malignancies, and the most common treatment received was radiation therapy alone ($\underline{n} = 265$, 66.9%). The interviews included questions concerning demographic information (age, gender, race, socioeconomic status), medical information (diagnosis, treatment, and Karnofsky Performance Status [KPS]), perceptual QOL (from the Andrews and Withey [1976] surveys on well-being), and health status (current patient perception). When compared with the age-adjusted baseline, 12% more of the patients were retired or disabled ($\underline{n} = 138$, 34.8%). The results revealed that satisfaction with QOL was no less ($\underline{p} \geq .05$) in the patient sample than in the baseline population. Patient perceptions of QOL at three, five, and 10 years after treatment did not differ significantly ($\underline{p} > .05$). Although this study supports the contention that QOL in patients cured of cancer for greater than three years is not significantly different than it is in others without malignant diseases, it does not assess the impact of treatment on QOL in the period

immediately following treatment. This short term impact would be particularly important in cancer patients having a projected survival of less than three years, such as lung cancer patients.

Lewis (1983) studied the association between experienced personal control and QOL in 57 terminally ill cancer patients. Most of the subjects had breast cancer ($n = 14$, 25%) or lung cancer ($n = 13$, 23%), and 28 (64%) had been diagnosed for one year or less. Four instruments were used in this study: (a) Rosenberg's Self-Esteem Scale (SES), which measures self-acceptance; (b) the Purpose-In-Life Test (PIL), which measures perceptions of meaning and purpose in life; (c) the Anxiety Scale, which measures perceived situational anxiety; and (d) the Health Locus of Control Scale, which measures expectations regarding sources of control for health-related reinforcements. The results revealed that those who experienced greater personal control over life had significantly lower levels of anxiety ($r = -.30$, $p = .001$), higher levels of self-esteem ($r = -.33$, $p = .001$), and higher levels of purpose in life ($r = -.45$, $p = .001$). Lewis concluded from these results that the experience of personal control is significantly associated with QOL. A major limitation of this study is that Lewis

did not clearly identify the basis for equating QOL with levels of self-esteem, purpose in life, and anxiety rather than using a multidimensional conceptualization of QOL that includes physical, psychological, social, and spiritual well-being; therefore, the validity of the conclusion is questionable.

The QOL of terminally ill cancer patients was studied in 114 patients from hospital-based palliative care units in Canada and 1121 hospice patients who were community residents in the United States (Morris, Suissa, Sherwood, Wright, & Greer, 1986). Because many patients in the terminal phase of illness lose the ability to communicate, data were gathered from interviews and written questionnaires completed by the hospice patients' primary care providers and the hospital patients' attending physicians and nurses at bi-weekly intervals. Instruments used to assess QOL included the Spitzer QOL Index (S-QLI), the KPS Scale, and investigator-created scales measuring awareness, mobility, discomfort, emotional QOL, and social QOL. It was found that mean QOL scores deteriorated over time (no significance levels reported), particularly in the period between one and three weeks prior to death. Approximately 20% of patients did not experience extremely low QOL even in the week preceding death. A limitation of

this study is that patient self-perceptions of QOL were not assessed; therefore, it is unclear whether care provider assessment of patient QOL was congruent with that perceived by the patient. Because no statistical analysis of changes in mean QOL was included, the significance of the reported findings is unclear.

Coates et al. (1992) studied the relationship between QOL and survival in 262 patients with metastatic breast cancer receiving chemotherapy. In a previous study (Coates et al., 1983) performance status (PS) using the Eastern Cooperative Oncology Group (ECOG) scale ($p \leq .001$) and metastases ($p \leq .001$ to $p = .02$) were significant predictors of patient survival. In this study, baseline and follow-up QOL scores were based on patients' completion of linear analogue self-assessment (LASA) scales measuring physical well-being (PWB), mood, pain, nausea and vomiting (NV), appetite, and overall QOL and on physicians' completion of the S-QLI. In univariate analyses using a multiple linear regression model, patient LASA scores for PWB ($b = -.019$), mood ($b = -.014$), NV ($b = -.019$), appetite ($b = -.014$), and overall QOL ($b = -.014$) and physician S-QLI ($b = -.263$) assessments were significant predictors of subsequent survival ($p \leq .001$ to $p = .013$). Using a multivariate linear regression model, the baseline PWB ($b = -.012$, $p =$

.01) and QOL ($b = -.169$, $p = .02$) were significant independent predictors of survival but PS ($p = .34$) was not. These results may indicate that different aspects of prognostic information are measured by patient assessment of PWB and physician assessment of S-QLI. Correlations between patient and physician assessments of QOL were not reported.

Hughes (1993) studied the impact of diagnosis and treatment on 52 early stage breast cancer patients' uncertainty, functional status (FS), and QOL. QOL was measured using the Ferrans and Powers QOL Index (FP-QLI) at the time of diagnosis and eight weeks after surgery (modified radical mastectomy or lumpectomy followed by XRT). Analysis of the data revealed that, although uncertainty ($F(1,51) = 4.51$, $p \leq .05$) and the physical functioning ($F(1,51) = 27.09$, $p \leq .001$), social functioning ($F(1,51) = 4.55$, $p \leq .05$), and role functioning aspects of FS decreased over the treatment course, overall and domain-specific aspects of QOL did not change significantly. These results indicate that although certain aspects of ability to function may have decreased, patients' satisfaction with their functioning remained unchanged. The conclusion drawn from this study was that QOL is a subjective concept that is not necessarily tied to objective measures.

Sugarbaker, Barofsky, Rosenberg, and Gianola (1982) conducted a study of 26 patients with soft tissue sarcoma. It was hypothesized that patients undergoing limb-sparing therapy would experience higher levels of QOL than those undergoing amputation. Participating patients were randomly assigned to treatment with either limb amputation plus chemotherapy or limb-sparing surgery plus high-dose XRT and chemotherapy. The following instruments were used to assess patient status when they had stabilized after therapy (one to three years): Psychosocial Adjustment to Illness Scale (PAIS), Sickness Impact Profile (SIP), Barthel Function Scale, and Katz Activities of Daily Living (ADL) Scale. Clinical assessment of mobility, pain, sexual relationships, and treatment trauma were also obtained. Analysis of these assessments using the Mann-Whitney statistic revealed amputees scored better on the SIP on emotional behavior ($p \leq .05$) and on body care and movement ($p \leq .01$), on the Katz ADL on functioning ($p = .051$), and on the PAIS on sexual functioning ($p \leq .025$) than those who underwent limb-sparing therapy. It was concluded from these results that the investigators' hypothesis that QOL would be improved in sarcoma patients receiving limb-sparing therapy was not supported. Of note is that the investigators clearly state that they had decided not to measure well-being,

satisfaction, or happiness in the study; however, they use the term QOL to refer to the phenomena studied. Because satisfaction and well-being are typically considered to be defining attributes of QOL, it would appear that the investigators conclusions should relate more to functional status than QOL.

The results of the Sugarbaker et al. study (1982) were used to modify the limb-sparing surgery, radiation therapy, and physical therapy sarcoma patients received. In a study of 39 patients with sarcoma involving the lower extremity, use of high-dose XRT without reduction of field size, extensive surgical resection, and little physical therapy (standard treatment) was compared with use of high-dose XRT with field size reduction, "refined" surgical resection, and intensive physical therapy (modified treatment) (Hicks, Lampert, Gerber, Glatstein, & Danoff, 1985). Analysis using the Chi-square statistic revealed that these changes in limb-sparing therapy resulted in significant improvement in function ($p \leq .02$) for patients receiving modified treatment when compared with those receiving standard treatment. As in the Sugarbaker et al. study (1982), this study did not assess satisfaction or well-being of the patients.

The impact of a 96-hour chemotherapy protocol on functioning, life-style, and QOL of soft tissue sarcoma

patients has been studied (Arzouman, Dudas, Ferrans, & Holm, 1991). Fifteen patients who had received the chemotherapy protocol in the 17 years prior to the study completed the FP-QLI-Cancer Version and the Functional Living Index-Cancer (FLIC). The results indicated that although patients' QOL during chemotherapy was reported as having been low, it improved after the completion of the chemotherapy.

Comparison of the mean subscale scores on the FP-QLI using one-way analysis of variance revealed that perceptions of QOL related to the family ($\underline{M} = 26.63$, $\underline{SD} = 6.76$) were significantly higher ($p < .05$) than perceptions of QOL related to health/functioning ($\underline{M} = 21.26$, $\underline{SD} = 4.25$) and socioeconomic status ($\underline{M} = 20.18$, $\underline{SD} = 3.39$). Length of treatment and financial burden were reported to have interfered most with the patients' lives. This study demonstrated the significance of social support in patients' perceptions of QOL. Assessment of patients' QOL prior to their starting treatment would provide a more complete description of the patterns of changes in QOL.

Browman et al. (1993) assessed the pattern of changes in QOL in 175 patients with locally advanced cancers of the head and neck receiving XRT treatment with or without concurrent chemotherapy. Patients were randomized to receive either continuous infusion chemotherapy or placebo

during the first and third weeks of XRT. The Head and Neck Radiotherapy Questionnaire (HNRQ), an instrument that measures morbidity and QOL in six domains using 22 Likert-type items, was administered weekly during the seven weeks patients received XRT and during the three weeks following treatment. Using a repeated-measures analysis of variance, a significant decrease was found in QOL during the seven week treatment period in all patients (F not reported, $p < .00001$). Patients receiving chemotherapy during XRT reported significantly lower QOL (F not reported, $p < .0007$) than those receiving placebo infusions. Plots of mean HNRQ scores reflected the decline in QOL during XRT and a subsequent increase following XRT, but QOL did not return to pre-treatment baseline levels (means not reported). In those who received chemotherapy during XRT, QOL appeared to return to a level comparable to that of patients who received placebo during XRT. The findings of this study reflect the changing patterns of QOL in patients with head and neck cancers receiving XRT treatments. QOL was not measured after the three week period following XRT; therefore, it is not known whether perceptions of QOL returned to their pretreatment baseline.

Quality of Life in Lung Cancer

Lung cancer is a devastating illness and the leading cause of cancer deaths. In a review of the literature using Medline, this investigator found that only 74(9%) of the 867 citations focusing on QOL in cancer were related to lung cancer. Many of these citations deal with general conceptual issues and discuss the importance of using QOL as an outcome measure in lung cancer treatment; however, few of these report results of data-based studies of QOL in lung cancer patients.

Bernhard and Ganz (1991a, 1991b) have reviewed psychosocial issues in lung cancer patients. After reviewing studies of personality traits in lung cancer patients, these authors could find no consistent evidence supporting the existence of a "lung cancer personality" nor other specific psychosocial risk factors for lung cancer. They found limited information regarding the psychosocial impacts of surgery or XRT in lung cancer patients; rather, most studies that even consider the effect of treatment on these patients only address performance status. According to Bernhard and Ganz (1991b), the extension of disease-free survival and overall survival has historically taken precedence over treatment-related toxicities when cancer treatments have curative intent. Increased physician

interest in basing treatment decisions on toxicities of therapy and the need for palliation has clarified the need for alternatives to use of survival data and performance status for clinical decision making. As a result, in recent years, assessment of patients' subjective experiences as an estimation of treatment benefit has more frequently been incorporated into clinical trials.

Bergman, Sullivan, and Sorenson (1992) conducted a longitudinal study of QOL in 62 small cell lung cancer (SCLC) patients receiving chemotherapy. QOL was assessed prior to treatment and at three, six, and 12 months after treatment start using the European Organization for Research and Treatment of Cancer QOL Questionnaire (QLQ) and analyzed using Fisher's two-tailed non-parametric permutation test and the .05 level of significance. Overall tumor response rate during the study was 82%. There was no significant change in mean QLQ scores. Although physical functioning decreased after three months, the change was not significant. Significant changes were found only in social functioning, which decreased at 6 months ($p < .01$), and emotional functioning, which improved in 12 months ($p < .05$). Multivariate regression analysis revealed that emotional functioning and fatigue/malaise accounted for 57% of the variance in QLQ scores. Of note is that the sample

size decreased to 48 at three months, 34 at six months, and 21 at 12 months due to treatment toxicity, tumor progression, or death. The loss of data from those who might be presumed to have a decrease in QOL might have resulted in artificial inflation of the mean QLQ scores and decreased ability to detect significant changes. It is not clear if the data analysis method performed was a result of the attrition of subjects prior to completion of all measures or if this analysis was planned. An additional limitation of this study is that the experiment-wise level of significance was not held at .05 by using Bonferroni adjustment.

Geddes et al. (1990) studied QOL in 53 SCLC patients receiving either four or eight cycles of chemotherapy. Subjects completed a daily diary card which included eight questions that assessed symptoms related to treatment, symptoms related to disease, and general well-being. Differences in the two groups were analyzed using the Mann-Whitney U test and the .05 level of significance. In the group in whom chemotherapy was continued, symptoms related to disease and treatment and general well-being worsened progressively when compared with those who received only four cycles of chemotherapy. Subjects who received eight cycles of chemotherapy also reported significantly worse QOL

during inter-treatment periods in addition to during treatment. These results indicate that successive cycles of chemotherapy had a greater negative impact on perceived QOL and that these perceptions persisted through the periods between chemotherapy administrations. Attrition due to death or disease progression resulted in a final sample size of 41 subjects, possibly skewing results of the study.

Bleehen, Fayers, Girling, and Stephens (1989) compared QOL, adverse reactions to treatment, and survival in 151 patients with SCLC. Subjects were randomized to receive either immediate combination chemotherapy with XRT (40 Gy) or selective palliative treatment with chemotherapy and/or XRT only when symptom control was required. Adverse reactions to treatment included myelosuppression, nausea, vomiting, diarrhea, and stomatitis; these symptoms were more prevalent ($p < .001$) and severe ($p < .001$) in those who received immediate treatment (80% and 45%) compared with those who received palliative treatment (33% and 11%). Median survival was increased ($p < .001$ using the log-rank test) in those who received immediate treatment (32 weeks) compared with those who received palliative treatment (16 weeks). QOL was assessed at 3 weeks, 6 weeks, 3 months, and 6 months using both intermittent clinician assessment of overall condition, level of activity, and degree of

breathlessness, and daily patient assessment of overall condition, activity, mood, anxiety, and vomiting. QOL in those who received immediate treatment was better according to clinician assessment but was worse according to patient assessment when comparing proportions of two best ratings with two worst ratings in each category over all measures (p values and proportions not reported). These results indicate that although active treatment for SCLC increases survival, it also results in increased adverse reactions and decreased QOL. One limitation of the study is that the compliance with return of the diary cards used by patients to assess QOL was low (n = 74, 49%). Another limitation is that the QOL measures used in the study do not reflect the multidimensional nature of QOL.

QOL was compared in 95 NSCLC patients who were randomized to receive either chemotherapy or XRT (Kaasa, Mastekaasa, & Naess, 1988). A questionnaire measuring psychosocial well-being and global QOL was administered to subjects prior to the start of treatment and during weeks two, six, 14, 23, 33, 42, and 52. Because of decreased sample size (n = 58 at week 23), results after week 14 were unreliable. Differences between the two treatment groups at each time point were tested using a two-tailed Student's t-test. Psychosocial well-being and QOL scores in the second

week were significantly higher ($p = .04$ and $p = .02$) in the XRT group than in the chemotherapy group, but there was no difference at any of the other measurement points. In the chemotherapy patients, psychosocial well-being decreased significantly (p not specified) two weeks after starting treatment but QOL did not. The XRT patients demonstrated a gradual improvement in psychosocial well-being and QOL from the beginning of treatment as did the chemotherapy patients after the second week. One limitation of this study is that the XRT patients remained hospitalized during the entire three weeks of their treatment course, but the chemotherapy patients were discharged from the hospital the day after receiving chemotherapy. Results of this study support the apparent temporary nature of the effects of more toxic treatments of NSCLC. The significance of the study results needs further examination as it appears that no Bonferroni adjustment was incorporated in the multiple comparisons. An additional limitation of this study is that treatment groups were compared at each time point rather than assessing patients in the treatment groups over time in a repeated measures or split-plot factorial design. This method of data analysis may have been related to attrition of subjects due to death or withdrawal from the study prior to completion of all measures.

Kaasa and Mastekaasa (1988) reported further on the results of assessment of disease and treatment-related symptoms, physical function, and everyday activity in addition to the assessment of psychosocial well-being reported earlier in NSCLC patients receiving either XRT or chemotherapy. It was found that psychosocial well-being was moderately correlated with disease-related symptoms ($\underline{r} = -.48$ to $-.56$, $\underline{p} < .01$) but was uncorrelated with treatment-related symptoms ($\underline{r} = .01$ to $-.21$, $\underline{p} \geq .05$) during the first 14 weeks. It may be concluded that patients accepted the consequences of treatment as a necessary condition of the opportunity to be cured of cancer, but that they also were aware of improvement or progression of their disease. Although the tumor response rate in the XRT group (42%) was twice that of the chemotherapy group, there was no difference in overall survival. XRT would therefore appear to be the preferable treatment regimen since it offered more tolerable acute toxic effects than chemotherapy which provided no relative benefit in terms of response or overall survival.

The study of QOL in lung cancer has been limited. Many of these studies focused on the impact of chemotherapy on SCLC patients. The usefulness of these studies has also been limited by small sample sizes, attrition greater than

50%, and absence of analysis of changes in QOL within subjects.

Summary

Although lung cancer remains the leading cause of cancer deaths, combined-modality treatment of NSCLC has resulted in improved survival rates. These treatment regimens, which include some combination of surgery, chemotherapy, and/or XRT, have been accompanied by more severe early and late toxicities. Other than report of these toxicities, the effect of these treatments on patients' lives has received scant attention in the literature.

Quality of life has gained attention in recent years as an important outcome measure in the treatment of many health problems. Although no consensus has been reached regarding the definition of QOL or its measurement, several common attributes have been identified. Assessment of QOL should include patient perceptions of well-being in the physiological, psychological, sociological, and spiritual domains of life.

Despite increased interest in the study of QOL in recent years, there have been few studies of the impact on QOL of NSCLC treatment with XRT alone or in combination with

other treatment modalities. A study of the changes in perceptions of QOL in NSCLC receiving XRT alone or as part of combined-modality therapy may be valuable in identifying characteristics that would be useful in assessment of level of QOL and subsequent interventions to assist these patients in adapting to the treatment so that they can achieve an optimal level of QOL.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The purpose of this research study was to determine if perceptions of quality of life (QOL) change in patients with non-small cell lung cancer (NSCLC) receiving curative radiation therapy (XRT) alone or in combination with other treatment modalities. The independent variable, curative XRT treatments, was not manipulated. The dependent variable, perception of QOL, was measured before, during, and twice following completion of the XRT treatment course. These variables were studied using a descriptive, longitudinal design with repeated measures.

A descriptive research design is employed when there is lack of information regarding the variables of interest in a given population (Brink & Woods, 1989). Use of the term QOL is relatively new; it was not used as a key word in Medline, the computer-assisted search program for medical literature, until after 1975 (Spitzer, 1987). Although QOL has been recognized as a valuable outcome measure of cancer treatment, less than five percent of clinical trials prior to 1982 included a systematic assessment of QOL (Cella & Tulsky, 1990). There have been studies of QOL in lung

cancer patients (Bergman, Sullivan, & Sorenson, 1992) and QOL in patients receiving XRT (Danoff, Kramer, Irwin, & Gottlieb, 1983); however, there have been no studies of QOL in lung cancer patients receiving XRT with curative intent. The dearth of research regarding QOL in this population reinforced the appropriateness of utilizing a descriptive design when studying QOL in NSCLC patients receiving XRT.

According to Brink and Wood (1989), a prospective, longitudinal design is used in epidemiologic studies to follow a cohort of subjects over a period of time and measure variables that will be occurring during the course of the study. This type of design is typically used to measure changes in variables over time in a population. This study utilized a prospective, longitudinal design because the purpose of the study was to measure change in perceptions of QOL. Although the study did not span several years as is typical of longitudinal studies, it included measurements in each subject at approximately the same time intervals over a six-month time span.

A repeated measures experimental design involves obtaining repeated measurements of treatment effects using the same subjects (Winer, 1962). The advantage of the repeated measures design is that it provides for control of

differences between subjects by having subjects serve as their own controls. Although this research study did not fall in the category of experimental design because it did not include randomization or manipulation of variables, use of the repeated measures design provided for control of differences between subjects as QOL was measured in each subject before the XRT course began, during approximately the fourth week of treatment, and at approximately one month and four months after XRT was completed.

The major difficulty with this type of study is the lack of control over extraneous variables. If changes in perception of QOL are observed, they may be the result of some independent variable that is extraneous to the purposes of the study. However, if QOL is truly a multidimensional concept, attempting to limit the influence of these so-called extraneous variables would jeopardize the validity of the study.

Setting

This study was conducted in the radiotherapy clinic of a comprehensive cancer center located in southeast Texas. Cancer patients are referred to the cancer center by physicians throughout the United States as well as internationally. The radiotherapy clinic consists of XRT

treatment rooms containing machines that deliver ionizing radiation either by linear acceleration or by decay of a radioactive source, treatment simulation rooms where treatment fields are drawn on each patient, and private rooms where routine appointments with the attending radiation oncologist, teaching, and conferences with patients take place. Patients receive treatments and have appointments in this clinic between the hours of 7:00 AM and 5:00 PM on weekdays.

Population and Sample

The population consisted of all persons with a histologic diagnosis of NSCLC receiving curative XRT in the radiotherapy clinic of a comprehensive cancer center located in southeast Texas. In this clinic, during the five year period preceding the study, an average of 322 lung cancer patients started XRT each year (26 per month). Of these patients, an average of 273 per year (23 per month) had histologic diagnoses of NSCLC, and 49 per year (four per month) had SCLC. Of the NSCLC patients starting XRT, approximately 50% (11 per month) received treatment with curative intent.

NSCLC patients receive curative treatment daily on weekdays for approximately six weeks. After completion of

the treatment course, patients return for follow-up with the radiation oncologist approximately one month after treatment and then approximately every three months after that throughout the first two years after treatment.

Subjects were considered for inclusion in the study if they met the following criteria:

1. had a confirmed diagnosis of NSCLC,
2. had not previously been diagnosed or treated for cancer other than skin cancers,
3. had consented to be treated with curative XRT,
4. were 18 years of age or older, and
5. were alert, oriented, and able to comprehend and complete the questionnaire.

The sample size for this study was based on calculations of power using the Statistical Package for the Social Sciences (SPSS) (1990) for analysis of variance (ANOVA) for repeated measures using the multivariate approach. Subjects were recruited for the study until analysis of the four repeated measures of QOL revealed that a minimum power of .80 and significance level of .01 had been achieved.

Subjects for the proposed study were selected using the nonprobability, consecutive sampling technique. With this

technique, all subjects who met the inclusion criteria for the study and agreed to participate were included in the study. Use of a consecutive sample rather than a convenience sample limited introduction of selection bias and increased the probability that the sample was representative of the population (Hulley & Cummings, 1988). This technique was used instead of random sampling because of the limited number in the population as a whole, which was predicted to be approximately 11 patients per month based on review of population trends during the five year period preceding the study.

Subjects who had been enrolled in the study and subsequently developed metastatic disease prior to completing all four measurements were withdrawn from the study. Recruitment of study participants continued until all measurements were completed on a sufficient number of subjects to achieve a minimum power of .80 and experiment-wise significance level of .05 using the multivariate approach to ANOVA for repeated measures. This continued enrollment allowed for consecutive accrual of subjects in spite of attrition due to death, development of metastatic disease, or voluntary withdrawal from the study. All

subjects enrolled in the study who completed all four measures were included in the data analysis.

Protection of Human Subjects

Approval for exemption from review by the Human Subjects Review Committee at the Texas Woman's University was obtained from the investigator's research committee (Appendix A). The study involved questionnaire research that did not involve sensitive behaviors and did not present risk of harm or liability to subjects. Only adult outpatients were included in the study, and subjects' names were not recorded on the questionnaires. The study therefore met the requirements for exemption from review by the Human Subjects Review Committee at the Texas Woman's University as well as exemption from review by the Surveillance Committee of the cancer center where the data were collected.

The intent, protocol, and nature of patient participation in the study were fully explained to all potential subjects. Patients were assured that their care and treatment would in no way be affected by participation or nonparticipation in the study and that they were free to withdraw from the study at any time. Completion and return

of the questionnaires indicated patients' consent to participate in the study.

Names of study participants were kept confidential and were not recorded on the questionnaires. The names of participants were recorded only on the data sheets to allow for follow-up for repeated measures. All data obtained from study questionnaires were numerically coded to ensure confidentiality of study participants and to allow for collation with the data sheets. Completed data sheets and questionnaires were kept in a secure location only accessible by the researcher. The study did not present any risks to subjects, nor did subjects receive any direct or immediate benefits from participation in the study.

Instruments

The Functional Assessment of Cancer Therapy - Lung (FACT-L) (Cella, 1992; Cella et al., 1995; Cella et al., 1993) was used to measure QOL in this study. A data sheet developed by this investigator was used to record descriptive data.

Data Sheet

A data sheet developed by this investigator was used to record descriptive data (Appendix B). The subject's name

was recorded on the data sheet to allow for follow-up for the repeated measures, and the study code number was recorded to allow for matching with data from the FACT-L. Descriptive information was gathered by inclusion of the variables age, gender, and race for purposes of describing the sample. Because of the potential impact of emotional and economic support on perceptions of QOL, marital status, employment status, method of payment for medical care, and distance from home were assessed. Diagnostic characteristics provided descriptive information that may relate to perceptions of QOL. The independent variable, XRT treatment regimen, was assessed.

The data sheet incorporated nominal, ordinal, and interval/ratio level measurement. The following variables were measured at the nominal level: gender, race, marital status, employment status, method of payment for medical care, sequence of treatment modalities, and chemotherapy drugs. The following variable was measured at the ordinal level: tumor stage. The following variables were measured at the interval/ratio level: age, distance from home, time interval since diagnosis (diagnosis date), XRT dose, and chemotherapy cycles.

Functional Assessment of Cancer Therapy-Lung (FACT-L)

The FACT-L is a self-report instrument that was developed to measure QOL in people with lung cancer (Appendix C) (Cella, 1992; Cella et al., 1995; Cella et al., 1993). Most patients with a sixth grade reading level have been able to complete the questionnaire unassisted. There are 28 Likert-type items in five subscales in the general version of the FACT (FACT-G) that are the core of the disease-specific form. The five subscales are: physical well-being, social/family well-being, relationship with doctor, emotional well-being, and functional well-being. A sixth subscale containing nine items for additional concerns that are specific to patients with lung cancer is included in the FACT-L. Each item in the subscales is completed with a response on a five-point scale ranging from "not at all" to "very much". There are also six experimental items that are being evaluated for possible use in weighting subscale scores; these items ask patients to rate the importance of each subscale in affecting their QOL and are rated on a 10-point scale ranging from "not at all" to "very much so".

Scoring of the FACT-L involves summing scores in each subscale after making appropriate reversals. Subscale scores are obtained by multiplying the sum of the item

scores by the number of items in the subscale then dividing by the number of items answered. Subscale scores are added to compute the total score. Higher scores are associated with increased satisfaction with QOL, and total scores for the FACT-L range from 0 to 148. The experimental items are not included in subscale scores or in the total QOL score. All items on the FACT-L are measured at the ordinal level. Summation of the items to derive subscale scores and a total QOL score results in data that are considered at the interval level of measurement (Munro, Visintainer, & Page, 1986).

Psychometric properties have been described for the FACT-G (Cella, 1992; Cella et al., 1993) and for the FACT-L (Cella et al., 1995). Convergent and divergent validity were established for the FACT-G by evaluating the association between scores on the FACT-G and other measures (Cella et al., 1993). Scores on the FACT-G had a high correlation ($r = .79$) with scores on the Functional Living Index-Cancer (FLIC), reflecting convergent validity, and a low correlation ($r = .22$) with scores on a measure of social desirability, reflecting divergent validity.

Internal consistency has been evaluated for each of the subscales and for the total FACT-G score for a sample of 466

cancer patients (Cella et al., 1993). The alpha coefficients for the subscales ranged from .65, on the subscale measuring relationship with the physician, to .82, on the subscale measuring physical well-being. The alpha coefficient for the total FACT-G score was .89, reflecting high internal consistency. The FACT-L was administered to 58 lung cancer patients to evaluate internal consistency; for the nine lung cancer items, the alpha coefficient was improved from .52 to .68 by deleting the uncorrelated hair loss and regret about smoking items (Cella et al., 1995).

Test-retest reliability was evaluated for each of the subscales and for the total FACT-G score in a sample of 60 previously untested cancer patients (Cella et al., 1993). The retests were conducted within three to seven days of the initial test, and the timing was such that no patient received chemotherapy between the tests. Test-retest correlation coefficients ranged from .82 to .92 for the subscales and the total FACT-G score.

Content validity of the FACT-L was assessed by this investigator using the Index of Content Validity (CVI) (Waltz, Strickland, & Lenz, 1984). Eight experts in the care of lung cancer patients, having the minimum qualifications of a master's level of education and five

years of experience working with lung cancer patients, were asked to independently quantify the relevance of each item on the FACT-L in assessing QOL and the adequacy with which the instrument represents the concept QOL. The proportion of items rated as quite or very relevant by all raters was calculated to determine the CVI. CVI scores calculated for the individual items ranged from .75 to 1.00. The total CVI calculated for the FACT-L was .98 (336/344). Comments received regarding the adequacy of the FACT-L in assessing QOL indicated that there were no inadequacies. These findings provided adequate evidence of the content validity (Lynn, 1986) of the FACT-L in assessing QOL in NSCLC patients receiving XRT.

Internal consistency reliability of the FACT-L was assessed by this investigator in a pilot study in which eight NSCLC patients receiving curative XRT completed the FACT-L before XRT started, during approximately the fourth week of XRT, and at approximately one and four months after XRT was completed. The standardized alphas obtained for the FACT-L ranged from .84 to .94 which is considered acceptable evidence of reliability (Nunnally, 1967).

Data Collection

Prior to data collection, permission to conduct this research study was obtained from the investigator's research committee at the Texas Woman's University (Appendix D). A consecutive sampling technique was used to select subjects with NSCLC who would be receiving curative XRT. The intent, protocol, and nature of patient participation in the study were fully explained to all potential subjects. Patients were assured that their care and treatment would in no way be affected by participation or nonparticipation in the study and that they were free to withdraw from the study at any time.

Following patients' enrollment in the study, information for the data sheet was obtained by investigator review of the medical records. Patients were given a copy of the FACT-L and sufficient time to complete it after their understanding of the instructions had been confirmed. Completion and return of the FACT-L indicated patients' consent to participate in the study. QOL was assessed in patients agreeing to participate in the study prior to the start of XRT to establish a baseline measure of QOL for each patient. It then was measured in approximately the fourth

week of treatment and at the routine clinic follow-up visits one month and four months after treatment completion.

In order to allow for consecutive accrual of subjects in spite of attrition due to death, development of metastatic disease, or voluntary withdrawal from the study, subjects were enrolled in the study until all measurements were completed on a sufficient number of subjects to achieve a minimum power of .80 and experiment-wise significance level of .05 using the multivariate approach to ANOVA for repeated measures. All subjects enrolled in the study who completed all four measures were included in the data analysis. All data were numerically coded and entered into a computer for analysis.

Pilot Study

A pilot study was conducted by this investigator to determine the feasibility of the proposed research study, identify research design problems, and test the study instruments. The methodology of the pilot study was the same as that described for the major study with the exception of the sample size, inclusion of a consent form, and revisions based on the pilot study. In order to allow for consecutive accrual of subjects in spite of anticipated attrition, enrollment of subjects in the pilot study

continued until four measurements were completed on eight subjects.

The pilot study sample included eight NSCLC patients between the ages of 42 and 73 with a mean age of 58 years ($\underline{SD} = 12$). They were mostly white, married, males who were on leave of absence from their employment and lived an average of 432 miles ($\underline{SD} = 445$) from the cancer center. Most of these subjects ($\underline{n} = 5$, 62.5%) used private insurance to pay for medical care. These Stage IIIA ($\underline{n} = 3$, 37.5%) or IIIB ($\underline{n} = 5$, 62.5%) NSCLC patients were receiving XRT in four different treatment regimens. Total XRT doses ranged from 6000 cGy to 6960 cGy ($\underline{M} = 6336$, $\underline{SD} = 311$) delivered in an average of 32 fractions. Two additional subjects were initially enrolled in the pilot study but did not complete all four measures of the FACT-L because they discontinued treatments prior to completing the XRT course due to intolerable side effects and did not return for follow-up appointments. Mean FACT-L scores decreased from before to during XRT ($\underline{M}_1 = 97.38$ with $\underline{SD}_1 = 15.39$, $\underline{M}_2 = 95.48$ with $\underline{SD}_2 = 18.72$) and then increased following XRT ($\underline{M}_3 = 111.13$ with $\underline{SD}_3 = 16.08$, $\underline{M}_4 = 100.54$ with $\underline{SD}_4 = 22.88$); however, this was not a statistically significant difference ($\underline{F} = 3.616$, $\underline{p} = .10$, power = .45). Deviations from the normal distribution

were calculated for scores on the FACT-L and no significant differences from the normal distribution were found. No significant correlations were found between QOL and demographic or treatment-related data.

Several revisions in methodology based on the pilot study were included in the major research study. The possibility of NSCLC patients who had been diagnosed and treated for other malignancies had not been considered prior to the pilot study. Because of the concern that prior diagnosis and treatment for cancer might alter perceptions of QOL during treatment for a second malignancy, the decision was made to exclude from the study any patients who had been previously diagnosed and treated for cancer other than skin cancers.

The methodology for the pilot study proposed that all subjects would be given the FACT-L to complete while they were at the radiotherapy clinic for routine appointments. For that reason, two of the subjects who were enrolled in the study but discontinued treatments prior to completing the XRT course due to intolerable side effects and who therefore did not return for follow-up appointments were lost to attrition. To avoid further loss of subjects who might be presumed to be experiencing decreased levels of QOL

related to XRT treatment, the methodology of the major study was revised to include mailing questionnaires with return envelopes to obtain the follow-up assessments of QOL in the event that subjects withdrew from treatment or did not return for routine follow-up as scheduled.

Treatment of Data

Data from the data sheets and the FACT-L were numerically encoded, entered into a computer using SPSS (1990), and examined for accuracy. Data from the FACT-L were recoded to perform reversals of appropriate items (Cella, 1992).

The reliability of the FACT-L in NSCLC patients receiving XRT was evaluated in terms of internal consistency. Cronbach's alpha was calculated for the items of the FACT-L. Because the FACT-L is a new instrument, an alpha coefficient of $\alpha > .70$ was considered adequate evidence of reliability (Nunnally, 1967).

Descriptive statistics were used to summarize the data from the data sheets and the FACT-L collected in the study. This analysis included frequencies and appropriate measures of central tendency and dispersion.

The research question of this study, do perceptions of QOL change in NSCLC patients receiving XRT, was examined

using a multivariate approach to ANOVA for repeated measures. Five pairwise comparisons among mean QOL measures were planned (\underline{M}_1 with \underline{M}_2 , \underline{M}_1 with \underline{M}_3 , \underline{M}_1 with \underline{M}_4 , \underline{M}_2 with \underline{M}_3 , and \underline{M}_3 with \underline{M}_4); therefore, Bonferroni adjustment necessitated that the .01 level of significance per contrast be attained to hold the experiment-wise error rate below .05 (Maxwell & Delaney, 1990). The ANOVA is robust to violations of the assumption of normal distribution of the dependent variable; other assumptions for ANOVA are not applicable to the multivariate approach to repeated measures ANOVA (Maxwell & Delaney, 1990).

The relationship between QOL and all demographic and treatment-related data were assessed to determine whether an analysis of covariance (ANCOVA) would be necessary. Spearman correlation coefficients were calculated for nominal and ordinal level data, and Pearson's correlation coefficients were calculated for interval or ratio level data.

Summary

The purpose of this study was to determine if perceptions of QOL change in NSCLC patients receiving curative XRT alone or as a part of combined-modality treatment. The study utilized a descriptive, longitudinal,

repeated measures research design. Using a consecutive sampling technique, subjects were selected from the population of NSCLC patients receiving curative XRT at a comprehensive cancer center. The FACT-L was used to assess QOL in these patients prior to beginning XRT, during approximately the fourth week of treatment, and approximately one month and four months after treatment completion. A pilot study was conducted which revealed that the research study was feasible. Data were analyzed using descriptive statistics and a multivariate approach for repeated measures ANOVA.

CHAPTER 4

ANALYSIS OF DATA

The purpose of this study was to determine if perceptions of quality of life (QOL) change in non-small cell cancer (NSCLC) patients receiving curative radiation therapy (XRT) alone or as a part of combined-modality treatment. A data sheet was used to record descriptive data, and the Functional Assessment of Cancer Therapy-Lung (FACT-L) was used to assess QOL in these patients. Descriptive statistics were used to summarize the sample demographic data. Data related to QOL were summarized using descriptive statistics and analyzed using a multivariate approach for repeated measures analysis of variance (ANOVA). To determine whether an analysis of covariance (ANCOVA) would be necessary, correlations of QOL with demographic and treatment-related data were examined. Internal consistency reliability of the FACT-L and its subscales was assessed by calculation of Cronbach's alphas. Subscales of the FACT-L that demonstrated adequate reliability were further examined using the multivariate approach for repeated measures ANOVA.

Description of Sample

Although 31 subjects were enrolled in the study, two withdrew from XRT and elected not to continue the study, five developed metastatic disease, and one expired, resulting in a final sample size of 23 subjects who completed all four measurements of QOL. Those who completed the study met all sample inclusion criteria: all were patients who had a confirmed diagnosis of NSCLC, had not previously been diagnosed or treated for cancer, had consented to be treated with curative XRT, were 18 years of age or older, and were alert, oriented, and able to comprehend and complete the questionnaire.

Ages of sample subjects ranged from 40 to 73 years ($\bar{M} = 58$, $SD = 11$). The sample consisted primarily of white ($n = 22$, 96%), married (100%) males ($n = 16$, 70%). Most of these subjects were on leave of absence from work ($n = 10$, 44%) or had retired ($n = 9$, 39%). Medical expenses were paid mostly using Medicare ($n = 10$, 44%) followed by insurance ($n = 7$, 30%). The distance between subjects' homes and the cancer center ranged from 10 to 1180 miles ($\bar{M} = 276$, $SD = 303$, $Mdn = 160$). Table 1 further describes the demographic characteristics of age, gender, ethnicity, employment status, payment for medical care, and distance from home.

Table 1
Frequencies and Percentages of Demographic Information
of NSCLC Patients Receiving XRT (N = 23)

Variable	n (%)
<u>Age (years)</u>	
40 - 49	6 (26)
50 - 59	4 (17)
60 - 69	10 (44)
70 - 79	3 (13)
<u>Gender</u>	
Male	16 (70)
Female	7 (30)
<u>Ethnicity</u>	
White	22 (96)
Black	1 (4)
<u>Employment Status</u>	
Unemployed	1 (4)
Retired	9 (39)
Leave of Absence	10 (44)
Employed	3 (13)
<u>Medical Payment</u>	
HMO/PPO	2 (9)
Insurance	7 (30)
Medicare	10 (44)
Public Assistance	4 (17)
<u>Distance from Home (miles)</u>	
< 100	8 (35)
101 - 200	5 (22)
201 - 300	3 (13)
301 - 400	3 (13)
401 - 500	1 (4)
> 500	3 (13)

Subjects had been diagnosed within the previous six months with Stage IIIa ($\underline{n} = 8$, 35%) or IIIb ($\underline{n} = 15$, 65%) NSCLC. Five different regimens were used in the treatment of these subjects' NSCLC (Table 2). XRT doses used in these treatment regimens ranged between 5000 and 6960 cGy ($\underline{M} = 6280$, $\underline{SD} = 587$).

Table 2
Frequencies and Percentages of Treatment Regimens
of NSCLC Patients Receiving XRT ($\underline{N} = 23$)

Treatment Regimen	n (%)
XRT alone	1 (4)
Surgery then XRT	9 (39)
Surgery then Chemo with XRT	1 (4)
Chemo with XRT	8 (35)
Chemo then Chemo with XRT	4 (17)

Note. Chemo = Chemotherapy

Findings

The FACT-L was used to assess QOL in this study. Subjects completed the FACT-L prior to beginning XRT, during approximately the fourth week of treatment, and approximately one month and four months after treatment completion. FACT-L scores can range from 0 to 148 with higher scores reflecting higher levels of QOL.

Descriptive statistics were used to summarize QOL data. Scores on the FACT-L were lowest during XRT treatment ($\underline{M}_2 = 93.08$, $\underline{SD}_2 = 20.31$) and highest one month after completing XRT ($\underline{M}_3 = 112.08$, $\underline{SD}_3 = 18.73$). Minimum and maximum scores obtained using the FACT-L as well as the means and standard deviations for each measurement are presented in Table 3.

Table 3

Descriptive Statistics for FACT-L Scores of
NSCLC Patients Receiving XRT ($\underline{N} = 23$)

	Min	Max	Mean	<u>SD</u>
FACT-L ₁	53	141	102.71	21.00
FACT-L ₂	53	132	93.10	20.31
FACT-L ₃	53	132	112.10	18.73
FACT-L ₄	69	133	109.01	20.14

Note. Min = Minimum score; Max = Maximum score

Research Question

The research question of this study, do perceptions of QOL change over time in NSCLC patients receiving XRT, was examined using a multivariate approach to ANOVA for repeated measures. Preliminary analysis verified that QOL scores varied across the four measures [$\underline{F}(3, 66) = 11.58$, $\underline{p} < .0005$, power = .999]. Five planned pairwise comparisons among mean QOL measures were performed (\underline{M}_1 with \underline{M}_2 , \underline{M}_1 with \underline{M}_3 , \underline{M}_1 with

\underline{M}_4 , \underline{M}_2 with \underline{M}_3 , and \underline{M}_3 with \underline{M}_4). FACT-L scores were significantly lower during XRT treatment than before treatment, \underline{M}_1 with \underline{M}_2 , ($p = .006$) or one month after treatment, \underline{M}_2 with \underline{M}_3 , ($p < .0005$). FACT-L scores were also significantly higher one month after treatment than they were before treatment, \underline{M}_1 with \underline{M}_3 , ($p = .01$). The remaining two contrasts among QOL scores did not meet the necessary .01 level of significance. These findings suggest that QOL does change in NSCLC patients receiving curative XRT. Although QOL declines significantly during XRT, it improves following XRT to a level higher than prior to treatment and then returns to the pre-treatment level. The results of these comparisons are summarized in Table 4.

Table 4

Summary of Pairwise Comparisons of FACT-L Scores
of NSCLC Patients Receiving XRT ($N = 23$)

Comparison	SS	$F(1,22)$	p	power
\underline{M}_1 vs \underline{M}_2	1065.67	9.40	.006	.83
\underline{M}_1 vs \underline{M}_3	1009.57	7.92	.010	.77
\underline{M}_1 vs \underline{M}_4	457.07	2.22	.150	.30
\underline{M}_2 vs \underline{M}_3	4149.76	38.25	<.0005	1.00
\underline{M}_3 vs \underline{M}_4	108.05	1.00	.329	.33

Correlations

The relationships between QOL and demographic and treatment-related data were assessed to determine whether an analysis of covariance (ANCOVA) would be necessary. Pearson product-moment correlation coefficients were calculated for relationships that incorporated interval level data. Spearman correlation coefficients were calculated for relationships that incorporated nominal and ordinal level data. None of the correlation coefficients met the .05 level of significance; therefore, an ANCOVA was not indicated. Table 5 presents the correlation coefficients obtained for each of the relationships.

Table 5
Correlations Between FACT-L Scores and Demographic and
Treatment-Related Variables of NSCLC Patients
Receiving XRT ($N = 23$)

Variables	FACT-L ₁	FACT-L ₂	FACT-L ₃	FACT-L ₄
Age	.29	.33	.01	.05
Gender	-.08	-.04	-.18	.10
Race	-.03	.03	-.20	-.19
Marital Status	.15	.10	.30	---
Employment Status	-.03	-.14	.27	-.22
Medical Payment	.17	-.06	.06	-.29
Distance from Home	-.12	-.06	.09	-.15
Cancer Stage	.17	.33	.10	.08
Months Diagnosed	-.23	-.06	-.19	-.19
Treatment Regimen	.14	.28	-.01	.02
XRT Dose	.11	.01	.28	.10

Reliability of the Instrument

Although reliability of the FACT-L had previously been established, internal consistency was assessed in this study at each of the four measurement times. Standardized alpha coefficients for the FACT-L ranged from .85 to .96 reflecting adequate evidence of reliability. Internal consistency reliability at each of the four measurement times was also adequate for the subscales measuring physical well-being (PWB) (alphas .88 to .91) and functional well-being (FWB) (alphas .86 to .90). Table 6 presents standardized alphas obtained for the FACT-L and subscales.

Table 6

Standardized Alpha Coefficients for the FACT-L and Subscales

Scale or Subscale	Number of Items	Standardized alpha coefficients			
		Time 1 n = 17	Time 2 n = 15	Time 3 n = 11	Time 4 n = 12
FACT-L	37	.92	.85	.96	.91
PWB	7	.88	.91	.90	.87
SWB	7	.07	.29	.70	-.88
RWD	2	.48	.93	.42	---
EWB	5	.84	.41	.95	.83
FWB	7	.87	.85	.90	.89
LUNG	9	.52	.33	.78	.55

Note. SWB = Social Well-being, RWD = Relationship with Doctor, EWB = Emotional Well-being, LUNG = Lung Cancer Concerns

Subscale Findings

The FACT-L was designed to assess multidimensional QOL in lung cancer patients. It includes six subscales: physical well-being (PWB), social well-being (SWB), relationship with doctor (RWD), emotional well-being (EWB), functional well-being (FWB), and lung cancer concerns (LUNG). Scores on the subscales were generally lowest during XRT treatment and then increased following treatment. Minimum and maximum scores obtained for all of the subscales as well as the means and standard deviations for each measurement are presented in Table 7.

Subscales of the FACT-L demonstrating adequate reliability were further examined using the multivariate approach for repeated measures ANOVA. Preliminary analysis verified that PWB scores varied across the four measures [$F(3,66) = 11.80, p \leq .0005, \text{power} = .999$] as did the FWB scores [$F(3,66) = 22.26, p \leq .0005, \text{power} = 1.000$]. Five planned pairwise comparisons (\underline{M}_1 with \underline{M}_2 , \underline{M}_1 with \underline{M}_3 , \underline{M}_1 with \underline{M}_4 , \underline{M}_2 with \underline{M}_3 , and \underline{M}_3 with \underline{M}_4) were performed among PWB measures and among FWB measures. The results of these comparisons are summarized in Table 8.

Table 7

Descriptive Statistics for FACT-L Subscales of
NSCLC Patients Receiving XRT (N = 23)

	Min	Max	Mean	<u>SD</u>
PWB ₁	9	28	19.48	5.88
PWB ₂	5	25	16.35	5.86
PWB ₃	11	27	22.87	3.85
PWB ₄	4	28	21.52	1.02
SWB ₁	16	28	24.15	3.14
SWB ₂	16	28	22.81	3.63
SWB ₃	10.5	28	22.69	4.22
SWB ₄	14	28	23.62	4.03
RWD ₁	3	8	7.17	1.37
RWD ₂	2	8	6.96	1.53
RWD ₃	3	8	6.91	1.65
RWD ₄	3	8	6.78	1.68
EWB ₁	3	20	14.65	4.59
EWB ₂	7	20	14.57	4.13
EWB ₃	5	20	16.09	4.00
EWB ₄	9	20	15.40	3.62
FWB ₁	5	27	14.91	6.67
FWB ₂	2.8	21	11.85	6.38
FWB ₃	4	28	18.74	6.25
FWB ₄	5	28	18.83	7.13
LUNG ₁	10	31	22.35	5.56
LUNG ₂	7	34	20.86	5.83
LUNG ₃	7	32	23.78	5.89
LUNG ₄	11	33	22.87	6.00

Table 8

Summary of Pairwise Comparisons of FACT-L Subscale Scores
of NSCLC Patients Receiving XRT ($N = 23$)

Comparison	SS	$F(1,22)$	p	power
<u>PWB</u>				
\underline{M}_1 vs \underline{M}_2	112.70	7.20	.014	.73
\underline{M}_1 vs \underline{M}_3	132.26	8.59	.008	.99
\underline{M}_1 vs \underline{M}_4	48.02	2.40	.136	.32
\underline{M}_2 vs \underline{M}_3	489.13	33.12	<.0005	1.00
\underline{M}_3 vs \underline{M}_4	20.89	1.47	.237	.21
<u>FWB</u>				
\underline{M}_1 vs \underline{M}_2	108.15	10.99	.003	.89
\underline{M}_1 vs \underline{M}_3	168.34	15.33	.001	.96
\underline{M}_1 vs \underline{M}_4	176.09	11.89	.002	.91
\underline{M}_2 vs \underline{M}_3	546.37	46.97	<.0005	1.00
\underline{M}_3 vs \underline{M}_4	.09	.01	.911	.04

PWB scores were significantly higher one month after treatment than during, \underline{M}_2 with \underline{M}_3 , ($p < .0005$) or before treatment, \underline{M}_1 with \underline{M}_3 , ($p = .008$). The remaining three contrasts among PWB scores did not meet the necessary .01 level of significance. In other words, although PWB was lowest during XRT, it improved following XRT to a level higher than prior to treatment and then returned to the pre-treatment level.

FWB scores were significantly lower during XRT treatment than before, \underline{M}_1 with \underline{M}_2 , ($\underline{p} = .003$) or one month after treatment, \underline{M}_2 with \underline{M}_3 , ($\underline{p} < .0005$). FWB scores were also significantly higher one month after treatment than before treatment, \underline{M}_1 with \underline{M}_3 , ($\underline{p} = .001$), and this improvement was maintained four months after treatment, \underline{M}_1 with \underline{M}_4 , ($\underline{p} = .002$). The remaining contrast did not meet the necessary .01 level of significance. Although FWB declined significantly during XRT, it improved following XRT to a level higher than prior to treatment and then remained at this higher level.

Summary of Findings

A total of 23 subjects participated in this descriptive, longitudinal study to determine if perceptions of QOL change in NSCLC patients receiving XRT alone or as a part of combined-modality treatment. A data sheet was used to record descriptive data, and QOL was assessed using the FACT-L. QOL was assessed in these subjects prior to beginning XRT, during approximately the fourth week of treatment, and approximately one month and four months after treatment completion.

The research question of this study, do perceptions of QOL change over time in NSCLC patients receiving XRT, was

examined using a multivariate approach to ANOVA for repeated measures. The analysis revealed that perceptions of QOL did change significantly in NSCLC patients receiving XRT. QOL was significantly higher before treatment and one month after treatment than it was during XRT treatment. QOL was also significantly higher one month after treatment than it was before treatment.

Subscales of the FACT-L that demonstrated adequate reliability, the PWB and FWB subscales, were also examined using the multivariate approach for repeated measures ANOVA. PWB was significantly higher one month after treatment than it was during or before treatment. FWB was significantly higher before treatment and one month after treatment than it was during treatment. FWB was also significantly higher one month after treatment than before treatment, and this improvement was maintained four months after treatment.

CHAPTER 5

SUMMARY OF THE STUDY

Although lung cancer and its treatment exert a profound influence on many aspects of the patient's life, there has been scant research assessing the impact of lung cancer treatment on quality of life. The purpose of this study was to determine if perceptions of quality of life (QOL) change in non-small cell lung cancer (NSCLC) patients receiving curative radiation therapy (XRT). The conceptual framework utilized in this study was the Roy Adaptation Model (Roy, 1980; Roy & Andrews, 1991) in which the person uses coping mechanisms to respond to stressors that affect level of adaptation and perceptions of QOL. This chapter includes a summary of the study, discussion of the study findings, conclusions, and implications for nurses. The chapter concludes with recommendations for further study.

Summary

A descriptive, longitudinal design with repeated measures was used to study perceptions of QOL in NSCLC patients receiving curative XRT. Subjects were selected using a nonprobability, consecutive sampling technique in

the radiotherapy clinic of a comprehensive cancer treatment center located in southeast Texas.

Protection of human subjects was ensured by fully explaining the intent, protocol, and nature of participation in the study to all potential subjects. Patients were assured that confidentiality would be maintained during and after the study. Completion and return of study questionnaires reflected patients' consent to participate in the study.

The Functional Assessment of Cancer Therapy - Lung (FACT-L) was used to assess QOL in this study. FACT-L scores can range from 0 to 148 with higher scores reflecting higher levels of QOL. Subjects were asked to complete the FACT-L during regularly scheduled appointments prior to beginning XRT, during the fourth week of treatment, and approximately one month and four months after treatment. A data sheet was used by the investigator to record subjects' demographic information and diagnostic and treatment characteristics.

The research question of the study, do perceptions of QOL change over time in NSCLC patients receiving curative XRT, was examined using a multivariate approach to ANOVA for

repeated measures. Five planned, pairwise comparisons among QOL measures were performed.

Discussion of Findings

Although 31 subjects were initially enrolled in the study, the final sample size consisted of 23 subjects who completed all four measurements of QOL. Of the eight subjects who did not complete all four QOL measurements, two withdrew from XRT and did not continue the study, five developed metastatic disease, and one expired. The resulting attrition rate was 26% over the six-month study period.

Somewhat greater attrition rates were reported in the QOL literature related to lung cancer. Kaasa, Mastekaasa, and Naess (1988) reported 39% attrition at six months in a study of QOL in 95 NSCLC patients receiving either XRT or chemotherapy. In a study of QOL in 151 SCLC patients receiving chemotherapy, Bleehan, Fayers, Girling, and Stephens (1989) reported 51% attrition over the six-month study. Bergman, Sullivan, and Sorenson (1992) reported 23% attrition at three months, 45% attrition at six months, and 66% attrition at 12 months in a study of QOL in 62 small cell lung cancer (SCLC) patients receiving chemotherapy.

The smaller attrition rate in the present study may be explained by the data collection method. All participants

were enrolled and all questionnaires were administered by the researcher who was the advanced practice nurse for lung cancer patients receiving XRT at the cancer center in which the study was conducted. Although subjects were reminded at each measurement time that their continued participation in the study was entirely voluntary, the supportive nature of the nurse-patient relationship may have contributed to their willingness to complete the questionnaires.

Although the 26% attrition rate in this study did not affect the methodology or the planned analysis, the loss of subjects may have influenced the study results through the loss of QOL data. Examination of the FACT-L scores obtained prior to XRT (the only measure completed by all 31 subjects) revealed that the eight subjects who did not complete the study rated their QOL before XRT as better ($\bar{M}_1 = 114.08$, $\underline{SD}_1 = 19.66$) than the 23 subjects who completed the study ($\bar{M}_1 = 102.7$, $\underline{SD}_1 = 21.03$) and that this difference was significant ($\underline{t} = 3.38$, $\underline{p} < .05$).

The two subjects who withdrew from XRT cited severe side effects as their reason for withdrawal from treatment and might be presumed to have perceived a more marked decrease in QOL during treatment than subjects who completed XRT. This presumption could not be supported by the data

because no further measurements of QOL were obtained. The pattern of change after treatment in perceptions of QOL in the two subjects who withdrew from XRT was also not measured; however, if the patterns of these subjects were similar to those found in the literature, their QOL would be expected to return to the pre-treatment level (Arzouman, Dudas, Ferrans, & Holm, 1991; Bergman, Sullivan, & Sorenson, 1992; Browman et al., 1993; Hughes, 1993; Kaasa, Mastekaasa, & Naess, 1988).

The sample consisted primarily of white (\underline{n} = 22, 96%) males (\underline{n} = 16, 70%). The gender distribution of this study sample was similar to the expected 2:1 (male:female) ratio (American Cancer Society, 1996). The racial distribution of this study sample differed from the 1:1:0.5 (white:black:hispanic) ratio that might have been expected based on lung cancer incidence by race (American Cancer Society, 1996). The under-representation of black and hispanic patients may have been related to the study setting in the comprehensive cancer center. Perhaps a sample more representative of the lung cancer population might be obtained by conducting a study in community or county facilities.

Research Question

The research question of this study, do perceptions of QOL change over time in NSCLC patients receiving XRT, was examined using a multivariate approach to ANOVA for repeated measures. FACT-L scores were significantly lower during XRT than before treatment, \underline{M}_1 with \underline{M}_2 , ($\underline{p} = .006$) or one month after treatment, \underline{M}_2 with \underline{M}_3 , ($\underline{p} < .0005$). FACT-L scores were also significantly higher one month after treatment than before treatment, \underline{M}_1 with \underline{M}_3 , ($\underline{p} = .01$). The remaining two contrasts among QOL scores did not meet the .01 level of significance; however, the power was also insufficient to find a difference if it existed.

These findings indicate that QOL changed significantly in NSCLC patients receiving curative XRT. Subjects rated their QOL as lowest during XRT treatment ($\underline{M} = 93.10$, $\underline{SD} = 20.31$) and highest one month after XRT treatment ($\underline{M} = 112.10$, $\underline{SD} = 18.73$). No significant difference was found in subjects' perceptions of their QOL four months after treatment compared with one month after XRT ($\underline{p} = .33$) or before XRT ($\underline{p} = .15$); however, the .80 level of power was not attained for these two comparisons.

The study findings regarding the decrease in level of QOL during and subsequent increase following treatment are

consistent with other studies of QOL found in the literature. In a study by Arzouman, Dudas, Ferrans, and Holm (1991), sarcoma patients who had been treated with chemotherapy felt that their QOL had been low during treatment but improved following treatment completion. Browman et al. (1993) found that patients with cancers of the head and neck who received XRT with chemotherapy or with a placebo experienced decreased QOL during treatment but subsequent improvement following treatment completion. Although Kaasa, Mastekaasa, and Naess (1988) found similarly that NSCLC patients receiving chemotherapy experienced decreased QOL in the first two weeks of treatment followed by improved QOL, they found that NSCLC patients receiving XRT experienced improved QOL from the start of treatment.

The study findings of no difference in the level of QOL four months after treatment compared with before treatment are consistent with other studies of QOL found in the literature. Bergman, Sullivan, and Sorenson (1992) found that patients receiving chemotherapy for small cell lung cancer (SCLC) experienced no significant change in QOL at three, six, and 12 months when compared with pre-treatment QOL. Hughes (1993) found similarly that QOL in breast

cancer patients was no different eight weeks after surgery with or without XRT than it was prior to treatment.

The perception of decreased QOL during XRT may be a reflection of the toxicities associated with treatment (Cox et al., 1990; Dillman et al., 1990; Weisenberg, Gail, & LCSG, 1986). The most common acute toxicity associated with thoracic XRT is esophagitis (Weisenberg, Gail, & LCSG, 1986).

The findings of the present study are congruent with conceptual discussions of QOL found in the literature. Quality of life has been described both as a response to a flow of events (Wellisch, 1984) and as perceptions of reactions to multidimensional stressors (Bowling, 1991). In the present study, the diagnosis of NSCLC and its treatment constitute a series of stressors that precipitates a flow of events that influences the patient's perception of QOL. These descriptions of QOL and the findings of the present study are congruent with the conceptual framework of the study: the Roy Adaptation Model (Roy, 1980; Roy & Andrews, 1991).

In Roy's model, the person uses coping mechanisms to respond to stressors that affect level of adaptation and perceptions of QOL (Roy, 1980; Roy & Andrews, 1991). In the

present study, the NSCLC patient receiving XRT perceived that QOL was less than prior to XRT, representing an ineffective response. The regulator and cognator subsystems were then activated through the adaptive modes of physiologic function, self-concept, role function, and interdependence. The resulting perception of QOL following XRT as better than during or before XRT represents an adaptive response.

In the present study, although QOL was lowest during the XRT treatment course, it improved following XRT to a level higher than prior to treatment before returning to the pre-treatment level. One explanation for these findings is that the acute toxicities associated with XRT are often most severe during approximately the fourth week of treatment. It is, therefore, not unexpected that patients perceive that their QOL is lowest during that time. The finding that QOL was higher one month after treatment than prior to XRT was unexpected, but it may be related to patients' feelings of euphoria or relief after the acute toxicities have subsided but the memory of their severity is still fresh. Four months after XRT, when the memory of the severe toxicities is less immediate, patients' perceptions of QOL equilibrate

to their pre-treatment level as was found in the present study.

Subscales

The FACT-L was designed to assess multidimensional QOL in lung cancer patients. It includes six subscales: physical well-being (PWB), social well-being (SWB), relationship with doctor (RWD), emotional well-being (EWB), functional well-being (FWB), and lung cancer concerns (LUNG). Adequate evidence of reliability at each of the four measurement times was demonstrated for the PWB (alphas .88 to .91) and FWB (alphas .86 to .90) subscales.

Scores on the PWB and FWB subscales were further examined using the multivariate approach for repeated measures ANOVA. PWB scores were significantly higher one month after treatment than during treatment, \underline{M}_2 with \underline{M}_3 , ($p < .0005$) or before treatment, \underline{M}_1 with \underline{M}_3 , ($p = .008$). FWB scores were significantly lower during treatment than before treatment, \underline{M}_1 with \underline{M}_2 , ($p = .003$). FWB scores were also significantly higher one month after treatment than before treatment, \underline{M}_1 with \underline{M}_3 , ($p = .001$) or during treatment, \underline{M}_2 with \underline{M}_3 , ($p < .0005$), and this improvement was maintained four months after treatment, \underline{M}_1 with \underline{M}_4 , ($p = .002$).

These study findings indicate that, like QOL, PWB and FWB changed significantly in NSCLC patients receiving XRT. Perceptions were rated as lowest during XRT for both PWB ($\underline{M}_2 = 16.35$, $\underline{SD}_2 = 5.86$) and FWB ($\underline{M}_2 = 11.85$, $\underline{SD}_2 = 6.38$). Perceptions of PWB were highest one month after XRT ($\underline{M}_3 = 22.87$, $\underline{SD}_3 = 3.85$), and perceptions of FWB were highest four months after XRT ($\underline{M}_4 = 18.83$, $\underline{SD}_4 = 7.13$).

The study findings regarding decreased PWB and FWB during treatment are consistent with other studies found in the literature. In a 1992 study by Bergman, Sullivan, and Sorenson, SCLC patients receiving chemotherapy experienced decreases in physical, social, and emotional function. Hughes (1993) found that physical, social, and role function decreased over the treatment course in breast cancer patients undergoing surgery with or without XRT.

The study findings regarding changes in PWB and FWB in NSCLC patients receiving XRT are also congruent with the Roy Adaptation Model (Roy, 1980; Roy & Andrews, 1991). In the present study, the NSCLC patient receiving XRT perceived that PWB and FWB were less than prior to XRT, representing an ineffective response. The regulator and cognator subsystems were then activated through the adaptive modes of physiologic function, self-concept, role function, and

interdependence. The resulting perceptions of PWB and FWB following XRT as better than during or before XRT represent adaptive responses.

In the present study, although PWB and FWB were lowest during the XRT treatment course, both improved following XRT to a level higher than prior to treatment. Although PWB returned to the pre-treatment level, the higher level of FWB persisted four months after XRT completion. Again, these findings might be explained by the occurrence of the most severe, acute toxicities of XRT during approximately the fourth week of treatment. It is, therefore, not unexpected that patients perceive that their PWB and FWB are lowest during that time. The finding that PWB and FWB were higher one month after treatment than prior to XRT was also unexpected but may again be related to inflation of perceptions of PWB and FWB in light of the recent memory of severe side effects. Four months after XRT, when the memory of the acute toxicities is more distant, patients' perceptions of PWB equilibrate to their pre-treatment level as was found in the present study. The persistently elevated FWB four months after XRT was also unexpected but may be related to a greater appreciation of normal life

activities after surviving the impact of the lung cancer diagnosis and its rigorous treatment.

Because adequate evidence of internal consistency reliability was not demonstrated for all FACT-L subscales in this study, the pattern of change of all domains of QOL was not fully analyzed. Preliminary review of the correlation matrices for the SWB, EWB, and LUNG subscales suggested that these subscales, particularly the SWB and LUNG subscales, may have been measuring more than one concept. The inadequate internal consistency of the RWD subscale in this study may be related to the fact that many physicians are involved in NSCLC patients' care before, during, and after their XRT: general practitioners, thoracic medical oncologists, thoracic surgeons, and radiation oncologists, among others. The presence of family members while patients were completing the questionnaires may also have influenced the responses to items on the SWB and EWB subscales and thus influenced the internal consistency of these subscales.

Examination of the mean subscale scores revealed that perceptions of SWB, EWB, and lung cancer concerns were generally worst during XRT treatment and then improved following treatment. Improvement in the psychosocial domains of QOL following XRT in this study may have been

related to patients' return to their home environment and increased availability of their familiar support systems. Improvement in concerns related to lung cancer following XRT may have been a result of decreased lung cancer tumor burden causing a decrease in lung cancer symptoms.

Similar results related to the psychosocial domains of QOL have been reported in the literature. In a study of QOL in NSCLC patients receiving chemotherapy or XRT, psychosocial well-being of chemotherapy patients decreased two weeks after starting treatment and then increased (Kaasa, Mastekaasa, & Naess, 1988). Bergman, Sullivan, and Sorenson (1992) found that social functioning of SCLC patients receiving chemotherapy was decreased six months after starting treatment and emotional functioning was increased at 12 months. Hughes (1993) found that both social and role functioning decreased over the treatment course in breast cancer patients who underwent surgery with or without XRT.

Conclusions and Implications

Lung cancer and its treatment are stressors that exert a major impact on patients' lives. Conclusions derived from the findings of this study and implications for nursing practice are presented in this section.

Conclusions

Based on the findings of this study, the following conclusions were drawn:

1. Quality of life changes in NSCLC patients receiving curative XRT.
2. Patients with NSCLC perceive that their quality of life is decreased during treatment with curative XRT.
3. Quality of life in NSCLC patients improves one month after treatment with curative XRT to a level higher than prior to treatment.
4. Quality of life in NSCLC patients receiving XRT is no different four months after treatment than it was prior to treatment.

Implications

Although the findings of this study need further research validation, the following implications for nursing practice were derived from the study conclusions:

1. Nurses caring for NSCLC patients receiving curative XRT need to assess patients' available coping strategies and level of adaptation and QOL prior to their starting XRT.

2. NSCLC patients receiving curative XRT need to be taught about the expected side effects of treatment that may affect their QOL and how to manage them.
3. Nurses need to implement interventions to minimize side effects of treatment and maximize patients' coping strategies when they are caring for NSCLC patients receiving curative XRT.

Recommendations for Further Study

Recommendations for future research concerning quality of life in NSCLC patients receiving curative XRT were generated from this descriptive study:

1. Replication of this study using a random sampling technique should be undertaken to increase the generalizability of the findings beyond the study sample.
2. This study should be replicated with a larger sample size to allow for further testing of subscale reliability and, therefore, further assessment of patterns of change in all domains of QOL.
3. Replication of the study with a larger sample would allow for further assessment of relationships between QOL and demographic and treatment-related characteristics with power adequate to detect significant correlations if they exist.

4. The study should be replicated in community and county XRT treatment facilities to increase the likelihood that a sample more racially representative of the lung cancer patient population might be obtained.

5. A study should be conducted in which QOL is measured prior to any portion of combined-modality treatment regimens for NSCLC to determine the influence of these treatments on perceptions of QOL before, during, and after XRT.

6. A study should be conducted to assess the QOL of NSCLC patients receiving curative XRT who develop metastatic disease.

7. Investigational studies need to be undertaken to test whether nursing interventions can better control symptoms and improve QOL in NSCLC patients while they are receiving curative XRT.

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APPENDIX A

Exemption from HSRC Review

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON
HUMAN SUBJECTS REVIEW COMMITTEE - HOUSTON CENTER

EXEMPT FROM HSRC REVIEW

If it is the decision of the research committee (for student research) or the department coordinator (for faculty research) that the proposed research is exempt from expedited or full review by the Human Subjects Review Committee (HSRC), please complete the following form. Three copies of this properly signed form must be submitted to the chair of the HSRC with the appropriate prospectus form.

Principal investigator: Lauri D. John, MSN, RN

Title of the Research: Quality of Life in Patients Receiving Curative Radiation Therapy for Non-Small Cell Lung Cancer

1. Give a brief description of the study (use continuation pages or attachments, if necessary). Describe the subjects, i.e., are they adults, institutionalized, minors. Describe the procedure that relates to the subjects' participation, i.e., what will the subjects do or what will be done to them.

Please see attached.

2. What are the potential risks to the human subjects involved in this research or investigation (use continuation pages if necessary) ?

Please see attached.

3. Is research being conducted for a nonuniversity sponsor? Yes _____ No X

Name of sponsor: _____

I certify that this research meets the requirements for being exempt from review by the HSRC as specified in the Human Subjects in Research: Institutional Review Board Policies and Procedures (Revised Fall 1994). Three committee members sign for paper or thesis, and all committee members sign for the dissertation research.

Anna Ylles _____ committee member
Chair, research committee. Date 2/12/96

K. Lynn H. Wick _____ committee member

Janice K. Hammer _____ committee member

or, in the case of faculty research

Department Administrator. Date _____
Department _____

Approved by HSRC Chair David W. ... Date Feb 15, 1996

HSRC 1995

APPENDIX B

Data Sheet

INITIAL DATA SHEET

Code # _____

Name _____

1. Age _____

2. Gender _____

3. Race _____

4. Marital Status _____

5. Employment status _____

6. Method of payment for medical care _____

7. Distance between MDACC and home _____

8. Diagnosis date _____

9. Stage _____ TNM _____

10. Primary treatment in order planned _____
(Surgery, XRT, Chemo, XRT + Chemo Con)

11. XRT total dose _____ cGy _____ Fx

12. Chemo drugs _____

13. Additional comments: _____

APPENDIX C

FACT-L

Your willingness to complete this form indicates that you have given consent for this research. The principal investigator will maintain data in confidence and assures you that confidentiality will be preserved and your name will not be revealed. You are not obligated to answer any question you consider too personal.

code # _____

FACT-L (version 2)

Below is a list of statements that other people with your illness have said are important. By filling in one circle per line, please indicate how true each statement has been for you in the past 7 days.

During the past 7 days:

PHYSICAL WELL-BEING

	not at all	a little bit	some- what	quite a bit	very much
1. I have a lack of energy	①	②	③	④	⑤
2. I have nausea	①	②	③	④	⑤
3. I have trouble meeting the needs of my family	①	②	③	④	⑤
4. I have pain	①	②	③	④	⑤
5. I am bothered by side effects of treatment	①	②	③	④	⑤
6. In general, I feel sick	①	②	③	④	⑤
7. I am forced to spend time in bed	①	②	③	④	⑤
8. How much does your PHYSICAL WELL-BEING affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

During the past 7 days:

SOCIAL/FAMILY WELL-BEING

	not at all	a little bit	some- what	quite a bit	very much
9. I feel distant from my friends	①	②	③	④	⑤
10. I get emotional support from my family	①	②	③	④	⑤
11. I get support from my friends and neighbors	①	②	③	④	⑤
12. My family has accepted my illness	①	②	③	④	⑤
13. Family communication about my illness is poor ..	①	②	③	④	⑤
If you have a spouse/partner, or are sexually active, please answer # 14-15. Otherwise, go to # 16.					
14. I feel close to my partner (or main support)	①	②	③	④	⑤
15. I am satisfied with my sex life	①	②	③	④	⑤
16. How much does your SOCIAL/FAMILY WELL-BEING affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

During the past 7 days:

RELATIONSHIP WITH DOCTOR

	not at all	a little bit	some- what	quite a bit	very much
17. I have confidence in my doctor(s)	①	②	③	④	⑤
18. My doctor is available to answer my questions ..	①	②	③	④	⑤
19. How much does your RELATIONSHIP WITH THE DOCTOR affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

Please turn to the next page.

code # _____

During the past 7 days:

	not at all	a little bit	some- what	quite a bit	very much
EMOTIONAL WELL-BEING					
20. I feel sad	①	②	③	④	⑤
21. I am proud of how I'm coping with my illness	①	②	③	④	⑤
22. I am losing hope in the fight against my illness	①	②	③	④	⑤
23. I feel nervous	①	②	③	④	⑤
24. I worry about dying	①	②	③	④	⑤
25. How much does your EMOTIONAL WELL-BEING affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

During the past 7 days:

	not at all	a little bit	some- what	quite a bit	very much
FUNCTIONAL WELL-BEING					
26. I am able to work (include work in home)	①	②	③	④	⑤
27. My work (include work in home) is fulfilling ...	①	②	③	④	⑤
28. I am able to enjoy life "in the moment"	①	②	③	④	⑤
29. I have accepted my illness	①	②	③	④	⑤
30. I am sleeping well	①	②	③	④	⑤
31. I am enjoying my usual leisure pursuits	①	②	③	④	⑤
32. I am content with the quality of my life right now	①	②	③	④	⑤
33. How much does your FUNCTIONAL WELL-BEING affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

During the past 7 days:

	not at all	a little bit	some- what	quite a bit	very much
ADDITIONAL CONCERNS					
34. I have been short of breath	①	②	③	④	⑤
35. I am losing weight	①	②	③	④	⑤
36. My thinking is clear	①	②	③	④	⑤
37. I have been coughing	①	②	③	④	⑤
38. I have been bothered by hair loss	①	②	③	④	⑤
39. I have a good appetite	①	②	③	④	⑤
40. I feel tightness in my chest	①	②	③	④	⑤
41. Breathing is easy for me	①	②	③	④	⑤
If you have ever smoked, please answer # 42.					
42. I regret my smoking	①	②	③	④	⑤
43. How much do these ADDITIONAL CONCERNS affect your quality of life?					
Not at all	①	②	③	④	⑤
Very much so					

APPENDIX D
Prospectus Approval

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON
HUMAN SUBJECTS REVIEW COMMITTEE - HOUSTON CENTER

**PROSPECTUS FOR THE DISSERTATION
APPLICATION TO HUMAN SUBJECTS REVIEW COMMITTEE**

(This form, completed and signed, must accompany student's dissertation research application to the HSRC)

This prospectus proposed by: Lauri D. John, MSN, RN

**Title: Quality of Life in Patients Receiving Curative
 Radiation Therapy for Non-Small Cell Lung Cancer**

Has been read and approved by the members of his/her research committee.
This research (check one):

 X Is Exempt from Human Subjects Review Committee review because:

this questionnaire research does not involve sensitive behaviors and does not involve risk of liability. Subjects will be adult outpatients whose names will not be recorded on the questionnaires.
(If exempt is selected for this research, complete form "Exempt From HSRC Review")

 Requires Full Human Subjects Review Committee review because:

 Requires Expedited Human Subjects Review Committee review because:

Research Committee:
Type name

Anne Young (Chair)

Sandra K. Hanneman

K. Lynn Wieck

Dean, College of Nursing

Signstore

James Young
Nandra K. Lammiman
K Lynn Hick

Signature

Date _____