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FEMALE BREAST CANCER PATIENTS' PERCEPTIONS OF PAIN
AND PHYSICAL WELL-BEING FOLLOWING SURGERY
FROM BREAST CANCER

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FEMALE BREAST CANCER PATIENTS' PERCEPTIONS OF PAIN AND PHYSICAL WELL-BEING FOLLOWING SURGERY FROM BREAST CANCER

By

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ABSTRACT

FEMALE BREAST CANCER PATIENTS' PERCEPTIONS OF PAIN AND PHYSICAL WELL-BEING FOLLOWING SURGERY FOR BREAST CANCER

By

Evelyn Hammond Bochenek

A non-experimental design utilizing data from a larger, longitudinal community cancer study was analyzed to describe older women's perceptions of pain and physical well-being within eight weeks of surgery for breast cancer. The sample population were women diagnosed with incident breast cancer (n=117). Perceptions of pain and physical well-being were measured using the Symptom Experience Index (Given, Given & Stommel, 1994) and the Medical Outcomes Study--FS36 (Stewart, Ware & Brook, 1981). The study was guided through use of the Impact of Pain on the Dimensions of Quality of Life conceptual model developed by Ferrell, Taylor, Grant, Fowler, & Corbisiero (1993).

Data were analyzed using basic descriptive statistics and bivariate descriptive statistics. The results of this study show that patients perceive a multitude of symptoms and physical limitations within the eight weeks following breast cancer surgery including a substantial amount of fatigue. Implications include the need to better manage symptoms and maximize functional abilities during the post-operative period.

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I would especially like to thank my daughter, Beth, and my parents, Barbara and Wally Hammond, for providing the support and understanding I needed to complete this program. It has been a lifetime dream.

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INTRODUCTION

Problem

Breast cancer is the most prevalent cancer in women today (Shapiro & Clark, 1995). The American Cancer Society (1996) estimates that during 1996, 182,000 women in the United States will be newly diagnosed with breast cancer; this is a two percent increase over the past decade. In Michigan, the incidence of breast cancer in females between 1985 and 1990 was 33,414 (Swanson, 1993). Breast cancer accounts for 31% of the cancer diagnoses in Michigan according to the Cancer Statistics reported by the Office of State Registry, Michigan Department of Public Health (MDPH) (1992). The incident cases of breast cancer in Michigan in 1990 occurring among those 65 years and older, was 49% (MDPH, 1992).

The diagnosis and treatment of breast cancer may include surgery and resulting changes in the presence of symptoms and physical functioning. Some third party payers are adopting guidelines to reduce the length of stay for breast cancer surgery procedures for Diagnosis-Related Groupings (DRG) 257-260 (Blue Cross Blue Shield of Michigan (BCBSM), 1995). Mandates require discharge from the hospital in 48 hours or less of the operative procedure for breast cancer surgical procedures, for the purpose of reducing costs (Doyle, 1995). Only six years ago (1990), the average length of stay for breast cancer surgery procedures was 3.7 days; the average length of stay for these same procedures during 1993 was 2.2 days (Michigan Hospital Association, 1995).

The diagnosis and treatment of breast cancer may include surgery, resulting in changes in the presence of symptoms and physical limitations. Older women are more likely to have surgery as the only modality of therapy for breast cancer but may also have more extensive disease at presentation than younger patients (Cohen, 1986). There are the increased morbidities that accompany age and those that accompany extensive breast cancer disease. Both may affect post-operative recovery, symptoms and functional ability.

The effects of pain on the patient and others has been well-documented in recent literature (Paice, Mahon & Faut-Callahan, 1991; McCaffery, 1991; Portenoy, 1989; Frank-Stromberg & Wright, 1984; Wyatt, Kurtz, & Liken, 1993). Pain is identified with decreased quality of life and decreased functioning; it affects daily activities, relationships, sleep and outlook on life (Timmerman & Sternbach, 1992; Spross, 1985). As the patient's length of stay in the hospital decreases, the need to assess the patient's perception of pain and physical well-being becomes even more important to primary care practitioners who maintain continuity with patients and coordinate care. The issue of early discharge from the hospital raises questions regarding the efficacy of pain management, other symptom management, i.e. nausea, constipation, fatigue, and the ability to physically function with such activities as walking, climbing stairs, and lifting.

The focus of this study is to describe patients perceptions of pain and physical well-being within eight weeks after surgical procedures for breast cancer. Physical well-being is defined in terms of functional ability, and symptoms. The issue of early discharge from the hospital, where health care professionals are available for physical and psychological support, raises questions regarding the efficacy of pain management and the perception of quality of life once discharged home. The eight week period after hospital discharge was chosen as a study point because it appears to reflect a milestone in the clinical and treatment course.

Purpose

The purpose of this study is to describe older women's perceptions of pain and physical well-being following surgical procedures for breast cancer within eight weeks of hospital discharge. By identifying the incidence of pain, symptoms and functional ability, areas can be identified to improve the patient's perception of physical well-being, by developing plans and expected outcomes for the management of symptomatology in the home setting and the improvement of outcomes and quality of life for clients may decrease costs for the health care system. Clinical nurse specialists/

nurse practitioners in primary care are in the forefront to provide efficient, cost-effective and appropriate health care services at the community level. The advanced practice nurse has the unique opportunity to play an important role in reducing readmissions to hospitals for symptom management and to improve the quality of care by appropriately assessing and managing symptoms in the primary care setting. To coordinate these efforts successfully, the clinical nurse specialist will need to utilize the available data and assimilate the roles of assessor, educator, collaborator, advocate, clinician, and case manager.

Statement of Research Questions

The specific research question is "What is the relationship between perceived pain and physical well-being as a component of quality of life within the first eight weeks of hospital discharge among women who have had breast cancer surgery?" A secondary question which will be examined is "Is there a difference in the relationship between pain and physical well-being by sociodemographic factors?"

Conceptual Definitions of Study Variables

The following variables were utilized in the study:

Quality of Life. Multi-dimensional state of being related to performance, personal attitudes and/or affective states, well-being and support including the domains of physical well-being, psychological well-being, spiritual well-being and social concerns (Ferrell, Wisdom & Wenzl, 1989).

Physical Well-Being. Physical well-being for the study consists of functional ability, and symptoms.

Pain. Pain is a common response to illness which requires nursing diagnosis and intervention; it is subjectively whatever and whenever the client describes (Ferrell, 1991; McCaffery & Beebe, 1989). A distinction is made among surgical pain (acute), chronic pain and cancer pain. Acute pain is defined as a protective mechanism with sudden onset; it is accompanied by a hope of recovery (McCance & Huether, 1990). Chronic benign pain is defined as that pain which extends beyond the usual course of a disease or injury (Bonica, 1992). Cancer pain or malignant pain is that pain associated with an advanced malignancy and experienced by two-thirds of cancer patients (Patt, 1992). Although breast cancer surgical procedures performed at Stage III or IV may include a component of cancer or malignant pain, for the purposes of the study, the type of pain referenced will be acute surgical pain.

Weakness. Weakness is a feeling of being weak, weary or exhausted or not able to function (Padilla, Ferrell, Grant & Rhiner, 1990). It may also include an increased need for sleep decreased ability to concentrate and an element of depression (Schroeder & Hill, 1993).

Fatigue. Fatigue is a symptom comprised of subjective weariness, exhaustion and lack of energy (Aistars, 1987).

Trouble Sleeping. Trouble sleeping is a persistent difficulty in falling asleep or staying asleep to the point that daytime functioning is compromised (Uphold & Graham, 1994).

Nausea. Nausea is an unpleasant feeling of impending vomiting (Graham & Uphold, 1994).

Poor Appetite. Poor appetite is the lack of, or interference of, the instinctive desire to eat and keep up organic life (Whitney, Hamilton & Rolfes, 1990).

Constipation. Constipation is a diminished frequency of defecation, incomplete evacuation or stools that are too hard or too small (Uphold & Graham, 1994).

Functional Ability. Nine physical functions related to activities of daily living including the ability to perform moderated activities (such moving a table, bowling or playing golf); vigorous activities (lifting heavy objects or participating in strenuous sports); lifting or carrying groceries; climbing several flights of stairs versus one flight of stairs; bending, kneeling or stooping; walking more than a mile; and walking several blocks versus one block.

Breast Cancer Surgery Procedures. All types of breast cancer procedures will be included. In the larger longitudinal study, patients were identified by primary site (breast) and whether breast surgery was employed as a treatment modality. All types of breast cancer surgery will be included as the data base for the larger, longitudinal study does not allow a distinction among the various types of breast cancer procedures at this time.

From a review of the literature, surgical pain and cancer pain for women with breast cancer are not well-managed (Liebeskind & Melzack, 1988; Bonica, 1990; Ferrell, Taylor, Fowler, Grant & Corbisiero, 1993; Paice, Mahon & Faut-Callahan, 1991). The National Institutes of Health Consensus Conference on pain management suggested that patients in the United States are under-treated for pain management (Ferrell, 1991). The United States Public Health Service through the Agency for Health Care Policy and Research (1992) has developed acute pain management guidelines for health care professionals in response to documented under-treatment of pain. The nurse practitioner in primary care needs to be concerned regarding postoperative pain because pain and physical well-being are concerns for the patients in primary care. Practitioners may be providing care for conditions which may be exacerbated by pain, symptoms or functional ability.

CONCEPTUAL FRAMEWORK

Pain Impact on the Dimensions of Quality of Life Model

The model, Pain Impact on the Dimensions of Quality of Life (Ferrell, Rhiner, Cohen & Grant, 1991) was used to develop a model for the study. The Ferrell et al. (1991) model builds on previous work by the researchers (Ferrell, Wisdom & Wenzl, 1989; Padilla, Grant & Ferrell, 1991; and Ferrell, Grant, Padilla, Vemuri & Rhiner, 1991). In 1989, Ferrell et al. studied quality of life as an outcome variable in 150 cancer patients including twenty-two breast cancer patients. Their findings using a quality of life tool demonstrated the following major factors were perceived by patients as associated with quality of life: psychological well-being, worry and nutrition.

In a study of 233 cancer patients over age 65 years of age with pain, Ferrell, Wisdom & Wenzl (1989) results indicated that there was a significant difference in quality of life between patients with and without pain and that pain was inversely related to functional status. This study reinforced the relationship of concepts of pain, functional status and overall quality of life.

Padilla, Ferrell, Grant & Rhiner (1990) studied 41 cancer patients (15% breast) to further define good or poor quality of life. The study generated three very broad categories of attributes of quality of life: physical, psychological and interpersonal well-being.

Then, in 1991, Ferrell, Grant, Padilla, Vemuri and Rhiner studied the experience of pain and perceptions of quality of life using the results of the three studies previously described. The domains or dimensions of quality of life were revised to include physical well-being and symptoms, psychological well-being, social concerns and spiritual well-being. The model illustrates the influence of pain on the four major dimensions of quality of life.

Ferrell, Rhiner, Cohen & Grant (1991) further refined the model in a study of the impact of cancer pain on family caregivers. Although the four dimensions of quality of life remained the same, the components of the dimensions were revised (See Figure 1).

Domain of Physical Well-being

The domain of physical well-being and symptoms is conceptualized as the components of functional ability, strength/fatigue, sleep/rest, nausea, appetite and constipation. Many of the these physical symptoms may be associated with breast cancer surgery, may cause profound symptom distress post-operatively. Symptom distress and functional limitations may severely threaten a patients' independence and life style. In a study of 66 patients with cancer, Ferrell, Ferrell, Ahn and Tran (1994) suggest that patients whose pain is managed are more likely to have better sleep, functional abilities and emotional and cognitive status.

Domain of Psychological Well-Being

Psychological well-being was conceptually defined to include the components of anxiety, depression, enjoyment/leisure, pain distress, happiness, fear, and cognition/attention. An important aspect of psychological well-being is meaningful because psychological distress and

Figure 1. Pain impact on the dimensions of quality of life (Ferrell, Rhiner, Cohen & Grant, 1991).

<table>
<tr><th>PHYSICAL WELL-BEING AND SYMPTOMS</th><th>PSYCHOLOGICAL WELL-BEING</th></tr>
<tr><td>Functional Ability
Strength/Fatigue
Sleep/Rest
Nausea
Appetite
Constipation</td><td>Anxiety
Depression
Enjoyment/Leisure
Pain Distress
Happiness
Fear
Cognition/Attention</td></tr>
<tr><td colspan="2">↖ ↗
PAIN
↙ ↘</td></tr>
<tr><th>SOCIAL CONCERNS</th><th>SPIRITUAL WELL-BEING</th></tr>
<tr><td>Caregiver Burden
Roles & Responsibilities
Affection/Sexual Function
Appearance</td><td>Suffering
Meaning of Pain
Religiosity</td></tr>
</table>

well-being are often altered by disease and treatment interventions.

Domain of Social Concerns

The domain of social concerns is comprised of caregiver burden, roles and responsibilities, affection/sexual function and appearance. Social concerns is sometimes referred to as interpersonal well-being. Affective changes experienced by patients may be attributed to the impact of surgery on relationships.

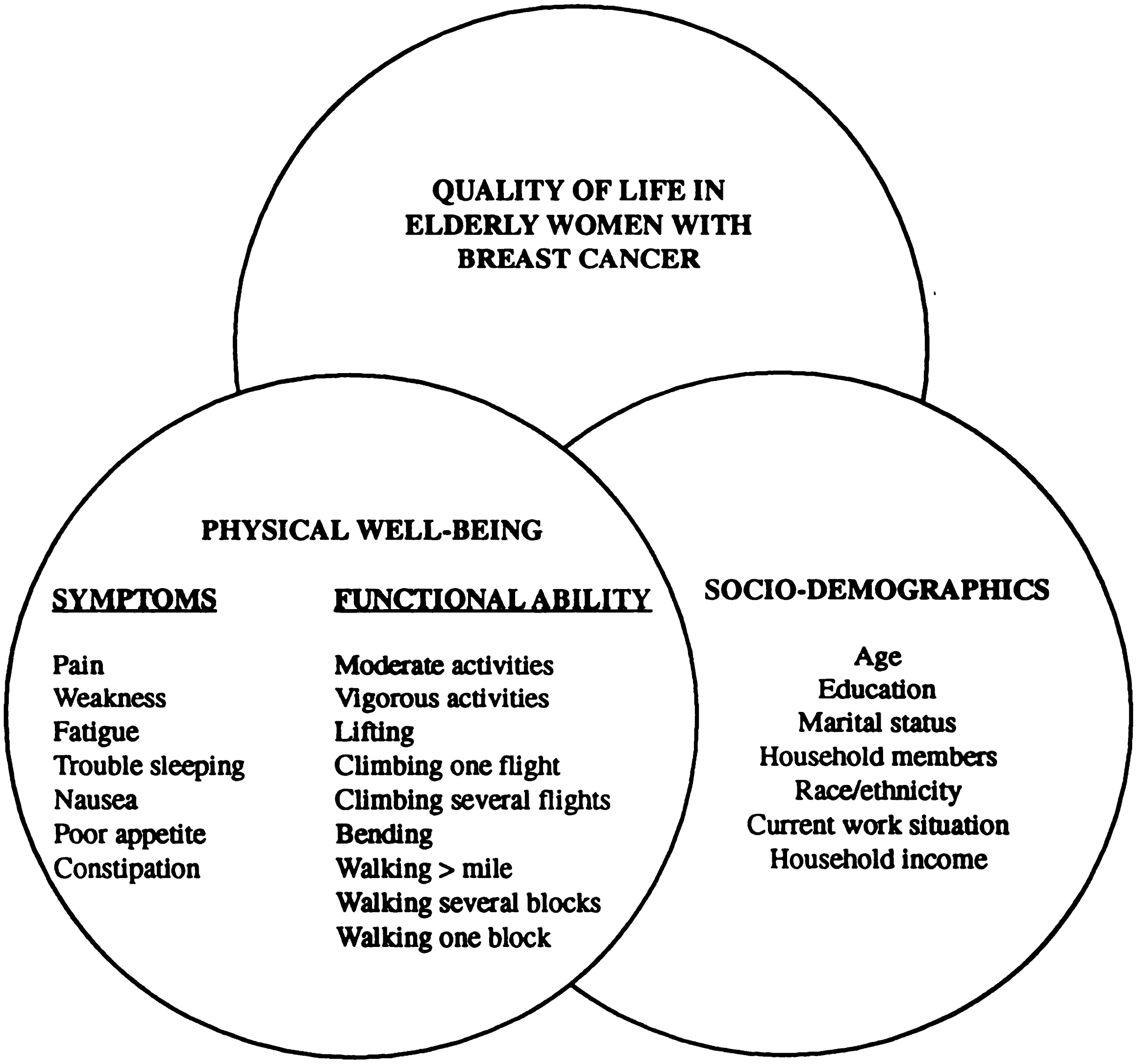
Domain of Spiritual Well-Being

The domain of spiritual well-being includes the components of suffering, meaning of pain and religiosity. Spirituality was originally included as part of psychological well-being but was reclassified a domain of its own as research showed suffering, religiosity and meaning of pain are frequently expressed by patients as quality of life. A diagnosis of cancer often generates a crisis of meaning, frequently affecting a persons ability to satisfactorily meet their spiritual needs of/for self-acceptance, relationships and hope.

Adaptation of the Pain Impact on the Dimensions of Quality of Life Model

The Impact on the Dimensions of Quality of Life model (Ferrell, et al., 1991) was adapted for the purposes of this study, to explore and describe older women's perceptions of pain and physical well-being following surgical procedures for breast cancer. While the Ferrell et al. (1991) model examines the relationship of pain to the four domains of quality of life in elderly cancer patients, it is the intent of this study to focus on a specific segment of the model, pain and physical well-being. A schematic representation of the adapted model is presented in Figure 2. The impact of pain on physical well-being was specifically chosen as the focus of the study as a result of personal interest and needs suggested by observations and literature. The conceptual model adapted for the study illustrates patients'

Figure 2. Adaptation of the Pain/Impact on the Dimensions Quality of Life Model.



perceptions of quality of life in relation to how pain corresponds with symptoms and functional abilities.

As the schematic prepresentation depicts, quality of life in elderly women with breast cancer may be impacted by physical well-being and patient demographics. Physical well-being is comprised of symptoms and functional abilities. The study includes pain as a symptom rather than a separate entity as in the Ferrell, et al. (1991) model. The adapted model also considers the relationship between pain and pain and physical well-being by sociodemographic factors.

REVIEW OF THE LITERATURE

A dearth of literature relative to pain and quality of life is found in the literature. Studies related specifically to pain and physical well-being which are focused on post-operative breast cancer surgery are few in number. A literature search revealed five research-based studies specifically relating to post-operative breast cancer surgery pain and well-being; four of these were printed in English.

Pain and Quality of Life

Boman, Bjorvell, Cedermark, Theve and Wilking (1993) studied the effects of early discharge from the hospital on women who have had mastectomy procedures for primary breast cancer. Although this study was developed to assess patient perceptions of discharge with silicone rubber suction drains in place, the investigators also included pain and other dimensions of psychosocial well-being and health after hospital discharge. Pain was assessed at two weeks after the operation as a point at or between unbearable and non-existent. The findings indicated that 93% of the women (n=84) discharged from the hospital early reported the presence of unmanaged pain as a problem at home two weeks after surgery. Although patients were asked about the presence of pain and its intensity, only the presence of pain was reported in the results.

Ferrell, Grant, Rhiner and Padilla (1992) studied 5772 hospital admissions to the City of Hope Medical Center, a designated comprehensive cancer center, which included 2977 unscheduled admissions. Symptom management, specifically pain and nausea, were cited as reasons for hospital admission and more than 50% of those unscheduled admissions occurred within two weeks of hospital discharge. Ferrell and colleagues noted symptom control in the home for cancer patients, especially pain management, would improve the quality of life for both the patient and caregiver. Another point of interest noted was that the use of high technology methods of care, while providing a means of maintaining physical comfort for the patient, also burdened the patients and caregivers because of the additional stress advanced technology creates.

In a study of 34 post-operative oncology patients diagnosed with breast cancer (56%) and other cancers (44%), Paice, Mahon and Faut-Callahan (1991) interviewed hospitalized patients regarding their post-operative pain experience. The results of this study suggested pain was not well-controlled. Seventy-one percent of patients responded they had pain. Thirty-eight percent reported moderate or severe pain at the time of the interview which was within one to 31 days after surgery (x, 5.38 days).

Kurtz, Kurtz, Given and Given (in press), investigated whether family caregiver reports of symptoms were in concordance with patient reports and whether certain other variables such as patient/caregiver depression, caregiver optimism and perceived impact on caregiver health would explain discrepancies in patient and caregiver reports. Of the 216 subject convenience sample, 27% represented breast cancer patients. Kurtz et al. (in press) suggest that education of caregivers to the nuances of the presentation of symptom distress is important to the reporting and interpretation of symptom distress to assure the appropriate symptom management may be initiated. Among the symptoms assessed (nausea, poor appetite, insomnia, fatigue, cough, constipation and diarrhea), pain was reported as present by 116 of the patients (53.7%).

Symptoms

Common side effects of general anesthesia and narcotics administration are constipation and nausea. Constipation is frequently perceived as a problem among the elderly and frequently report this system to health care providers (Ebersole & Hess, 1990). While opioid analgesics are the cornerstone of pharmacologic management for post-operative pain, patients (especially the elderly) report bowel function problems as a side-effect (AHCPR Guidelines, 1992).

Fatigue is a well-recognized phenomenon after surgery. Schroeder and Hill (1993) found in a study of 84 patients that a strong influence between prolonged post-operative fatigue in those patients diagnosed with cancer even after curative surgery as compared to those with benign disease. Fatigue becomes significant when it begins to have an adverse effect on a person's well-being and interferes with daily functions and relationships.

In defining the content domain of quality of life for cancer patients, Padilla et al. (1990) studied forty-one cancer patients (six of whom had breast cancer). Patients were asked what contributed to poor or bad quality of life. Patients reported feeling weak, disabled or not strong contributed to their perception of poor or bad quality of life. Most discussions of fatigue incorporate weakness as part of the definition of fatigue. Weakness in and of itself is not discussed.

Functional Ability

Functional ability is a special concern among the elderly. It is suggested that 45% of people age 65 years and older and living at home have some degree of functional limitation (Campbell & Thompson, 1990). Kurtz, Given, Kurtz and Given (1994) studied the interaction of age, symptoms and survival status on physical and mental health of patients with cancer (25.3% were breast cancer) and their families. Results of this study (n=208), patient age was not a significant factor for any of the variables. The results did suggest that symptoms proved to be the only significant predictor of functional dependencies in activities of daily living (f=9.47, p=0.002).

Satariano, Ragheb, Branch and Swanson (1990) studied 444 women to determine difficulties in functional ability reported by middle-aged elderly women with breast cancer. Results showed that women age 55-64 with breast cancer, after surgery, were more likely than the control group to report a greater problem with physical activities three months after surgery, especially in those activities involving upper-body strength. In subjects age 65-74, breast cancer subjects were twice as likely as controls to have difficulty with upper-body strength.

Mor, Wilcox, Rakowki and Hiris (1994) reported a longitudinal study of 7527 patients which involved aging, matched Medicare claims and six year functional status transition rates, and hospitalizations were calculated. Mor et al. (1994) found that more women than men experienced functional decline and institutionalization. In their study, Mor et al. (1994) found illness and perceived health (quality of life) are better indicators for future outcomes than age or current functional status.

Summary

In summary, these studies suggest that post-operative pain is not well-managed. Patients may be discharged from the hospital either with or developing both pain and other symptoms, or physical limitations. Patients and their families may be impacted. The need to improve post-operative pain and symptom management for women following breast cancer surgery is a facet of care needing attention by health care professionals from multiple disciplines including nurses in advanced practice. Nurses in advanced practice can play an important role in this effort at the individual, family and community level through education, advocacy, case management and research. The multidimensional characteristics and domains defining quality of life have been identified and been widely accepted. The relationship between pain and the other components of quality of life have not been systematically studied to assess the role or interactions of intervening variables such as weakness, fatigue, trouble sleeping, nausea, poor appetite and constipation specifically related to quality of life after surgery for breast cancer in elderly women. These interactions may be complex and must be clarified by systematic assessments of pain and other symptoms or functional ability.

The multidimensional domains and characteristics of quality of life have been identified and defined. The relationship between pain and other components of quality of life have not been systematically studied to assess the role or interactions of intervening variables such as weakness, fatigue, trouble-sleeping, nausea, poor appetite and constipation specifically related to quality of life after surgery for breast cancer in elderly women. These interactions may be complex and must be further clarified by systematic assessments of pain and other symptoms and/or functional abilities.

METHODS

Research Design

This study was a descriptive correlational study to explore and describe older women's perceptions of pain and physical well-being (symptoms and functional ability) within eight weeks of surgery for breast cancer procedures, using secondary data analysis from a larger, longitudinal community cancer study. The larger study is following incident diagnosis of breast, colorectal, lung and prostate cancer (5R01NCA0915-0, "Family Home Care for Cancer--A Community-based Model," - Barbara Given, PhD, RN, FAAN and Charles W. Given, PhD, Principal Investigators). This research project is a collaboration between Michigan State University (MSU) College of Nursing; College of Human Medicine, Departments of Family Practice, Medicine and Surgery; the Cancer Center at MSU (CCMSU); and the MSU Cancer Treatment Center (MSUCTC).

The sample size is comprised of 117 patients. Data was collected from patients by phone interview by eight weeks of hospital discharge.

Sample Procedures

The target population for this study is women having breast cancer surgical procedures. Criteria for inclusion of patients in the study include the following:

1. Female
2. New diagnosis - an incident case of breast cancer with breast cancer surgery as initial form of treatment
3. English-speaking
4. Cognitively intact
5. Age 65 years or over
6. No hospitalizations in previous 60 days for other problems
7. Assessment within eight weeks of surgery

Rationale for Point of Data Collection

Data were collected from patients within eight weeks of hospital discharge regarding pain management and the impact of pain on physical well-being, specifically physical symptoms and functional ability. The eight week point appears to reflect a milestone in the clinical and treatment course. Specifically, the observation point was selected to determine the patients' perceptions of pain and physical well-being within eight weeks of hospital discharge when surgical pain may still be problematic (Kroner, Krebs, Skov & Jorgensen, 1989).

Data Collection Procedures

Participants in the study were informed that they were participating in a longitudinal study that would involve several encounters by telephone by a nurse recruiter. They were told that participation was entirely voluntary and that they could withdraw at any point. Confidentiality was explained to the participants and informed consent was obtained. The subjects enrolled during the incident hospitalization.

Data Collection During Hospitalization

Nurse recruiters were identified to recruit patients during hospitalization. The nurse recruiters, following criteria for accrual, reviewed medical records and identified patients eligible for this research. Patients were enrolled while still in the hospital, and signed consents from the community were sent to Michigan State University (MSU). Patients were then followed for up to 52 weeks by the research team at MSU. Patients were recruited through 23 community hospitals affiliated with the College of Human Medicine, College of Nursing and Cancer Center at Michigan State University. Once identified by a nurse recruiter, each patient had the study described to her, a brochure given, and her consent obtained in writing. Once signed consents were obtained by Michigan State University, patients were then assigned to interviewers for data collection.

Training of Data Collectors

Nurses, medical students and epidemiology students were recruited and trained to be data collectors. The interviewers participated in extensive training sessions that included presentation of protocols and training manuals; practice sessions, taped interviews with each other; practice interviews with the principal investigator(s); and an audited interview with the initial client (Collins, Given, Given & King, 1988). On-going quality assurance measures included submission of one taped interview per month to assure protocols are followed; monthly booster sessions regarding protocols were held. Ten percent of actual interviews and records for each data collector were also checked by the principal investigator(s) or designees to assure that protocols relative to specific time frames for calls were followed reliably.

Operational Definition of Variables

For the purposes of this study, pain and physical well-being were operationalized as scores on the various tools used. Physical well-being for this study was defined as functional abilities such as lifting heavy objects or participating in strenuous sports, climbing several flights of stairs, or walking several blocks, and the symptoms of nausea, weakness, trouble sleeping, poor appetite, fatigue and constipation.

The symptoms of weakness, fatigue, touble-sleeping, nausea, poor appetite, and constipation, were operationalized as scores on relevant portions of the Symptom Experience Index (Given et. al, 1994) (See Appendix C). For the Symptom Experience Index, each symptom is reported as to presence, severity and the extent to which the symptom has disrupted regular daily activities. Subjects were asked if they experienced the symptom (1=yes, 2=no) and if so, how severe was it and the severity reported as mild, moderate or severe (range 1-3) where 1=mild, 2=moderate, and 3=severe.

Functional ability or activities of daily living, activities usually performed during the course of a day such as carrying groceries, moving a table, bending, and walking one block, were operationalized as scores on nine questions of the Medical Outcomes Study Health Status Questionnaire--SF36 (Stewart, Hay & Ware, 1988) (See Appendix B). Functional ability was assessed eight weeks after hospital discharge. Each functional ability was assessed as (3) Yes, limited a lot, or (2) Yes, limited a little, or (1) No, not limited at all. A mean for each category was calculated.

Sociodemographic data was collected. The parameters calculated included age, education, marital status, current work situation, household members and race/ethnicity (Appendix A).

Protection of Human Subjects

Subjects for the larger, longitudinal study include an equal number of breast, colorectal, lung and prostate cancer patients. The rationale for this selection was based on the lack of literature describing continuing care for elderly patients with these four common cancers. If cognitive deficits were present, patients were excluded from study participation. The research subjects were not compensated nor did they incur additional financial costs as a result of their participation in the study. No advertising was done to recruit study participants (See Appendix E for UCRIHS letter of approval).

The anonymity and confidentiality of study participants was safe-guarded in the following ways: 1) by use of subject identification numbers on all instruments, 2) by release of research data in aggregate form only, 3) by omission of agency names and/or identification in all presentations and reports, and 4) by not providing confidential interview data given by subjects back to the agency or participating physicians.

Patients were not placed at increased risk by participating in this study. Participation involved no physical activity by the patients. Subjects were free to decline participation and could withdraw from the study at any time with the assurance that their refusal to participate would in no way alter the care that they would receive from their home care agency, hospital or nurse practitioner or physician. Informed consent was obtained from each subject and a consent form signed. This study was approved by Michigan State University Human Subjects

Committee (See Appendix D for the UCRIHS letter of approval).

Instrumentation

A demographic instrument was utilized to collect sociodemographic information for the purposes of this study (Appendix A). To measure the patients' perceptions of pain and physical well-being, two instruments were used: the Symptom Experience Index and the MOS-FS36. The Symptom Experience Index, developed by Given et al. (1994) includes 34 common symptoms that are rated as to presence, severity and life disruption. The study, guided by the adaptation of the Pain Impact on Quality of Life model Ferrell et al. (1991), included only six of the symptoms: weakness, fatigue, trouble sleeping, nausea, poor appetite, and constipation. Patients were asked to report the presence of symptoms, and the severity of each symptom from moderate to severe (1-3).

The Symptom Experience scale is a modified version of McCorkle's (1978) Symptom Distress Scale (Kurtz, Given, Kurtz & Given, 1994). This measure has had limited reliability and validity testing. It has primarily been used to measure symptom distress in elderly cancer patients. In a study of 196 patients with cancer, the modified measure was found to have good reliability (alpha=.86) (Given, Stommel, Osuch, Kurtz & Kurtz, 1993). In another study of 150 cancer patients, Kurtz, Kurtz, Given and Given (1991) used a modified symptom scale that included the symptoms of cough bowel problems, pain severity of pain, nausea and severity of nausea. Kurtz et al. (1995) noted a reliability (alpha=.70) for the reduced scale. For the symptoms pain, nausea, fatigue, poor appetite, trouble sleeping, constipation and weakness, alpha is not reported because these are discrete symptoms of different body systems and reliability in the usual sense would not be expected. A coefficient alpha as low as .61 represents acceptable agreement if the instrument is not new (Knapp & Brown, 1995). Knapp and Brown (1995) further state that although there is considerable disagreement regarding the subject to number of variables ratio, the most commonly recommended ratio is ten subjects per variable.

The patient's functional status was measured with use of the Medical Outcomes Study--FS36 (Stewart, Ware & Brook, 1981). The SF36 is a 36-item, self-reporting multi-item scale measuring each of eight health care concepts (Ware & Sherbourne, 1992). The health concepts included in the survey are physical functioning; scoring as above and seven other parameters not under investigation in this paper are also included in the SF36.

The Medical Outcomes Study--FS36 (Stewart, Ware & Brook, 1981) has been widely used and tested and found to be psychometrically sound in a wide variety of patient populations (Stewart, Hay & Ware, 1988). The SF36 is a 36-item, self-report multi-item scale which measures eight health care concepts (Ware & Sherbourne, 1992). The health concepts addressed in the instrument which are a focus in this study are functional ability and role limitations. Nine functional ability items were used including vigorous activity, moderate activity, lifting/carrying, climbing several flights of stairs, climbing one flight of stairs, bending/kneeling, walking more than one mile, walking one block, and walking several blocks. Stewart, Hay and Ware (1988) compared reliability coefficients using Cronbach's alpha, for the items in the functional ability section of the measure. Alpha values ranged from .81 to .88. For the purposes of this study, Cronbach's alpha was computed for the nine physical limitations (alpha=.79).

RESULTS

Table 1 summarizes the sociodemographic data for the sample. Most subjects were Caucasian. Marital status was missing from the data provided for 76.9% of the sample. 80.3% of the sample had at least a high school education. About 65% of the subjects lived with another person, and most of the subjects were not employed. Although marital status was missing for 76.9% of the sample, the subjects may have considered that information captured in the question regarding household members, as approximately 50% responded that they lived with their spouse. Household income had no data available for 97.4% of the sample.

Research Question #1

To answer research question number one: What is the relationship between perceived pain and physical well-being

Table 1.

Sociodemographic Characteristics of the Sample (n=117)

Characteristics	Frequency	Percent
PATIENT AGE		
65-74 years	76	65.0
75-84 years	37	31.6
85+ years	3	2.6
No data available	1	<1.0
EDUCATION		
Less than high school	23	19.7
Completed high school	56	47.9
Greater than high school	38	32.4
MARITAL STATUS		
Married	16	13.7
Not married	11	9.4
No data available	90	76.9
HOUSEHOLD MEMBERS		
No one	41	35.0
Spouse	62	53.0
Other	14	12.0
RACE/ETHNICITY		
Caucasian	112	95.7
African-American	4	3.4
Not specified	1	<1.0
CURRENT WORK SITUATION		
Employed	7	6.0
Homemaker	29	24.8
Not employed	81	69.2
HOUSEHOLD INCOME		
$-4999	2	1.7
5000-9999	1	<1.0
No data available	114	97.4

within the first eight weeks of hospital discharge among women who have had breast cancer surgery, the frequency of occurrence and average severity of the individual symptoms for those reporting symptoms were computed (Table 2). The severity of the symptom was scored from one to three with

Table 2.

Symptom Severity of Sample (n=117)

SYMPTOMS	SEVERITY OF SYMPTOMS MILD=1	MOD=2	SEVERE=3	TOTAL SYMPTOMS PRESENT	NONE=0	AVERAGE SEVERITY REPORTED
Pain	29 (24.8%)	16 (13.7%)	1 (<1.0%)	46 (39%)	71 (61%)	1.39
Nausea	13 (11.1%)	4 (3.4%)	0	17 (4.5%)	100 (85.5%)	1.24
Fatigue	45 (38.5%)	26 (22.2%)	6 (5.1%)	53 (65.8%)	40 (34/2%)	1.49
Trouble-sleeping	16 (13.7%)	19 (16.2%)	6 (5.1%)	41 (35%)	76 (65%)	1.76
Poor appetite	12 (10.3%)	8 (6.8%)	2 (1.7%)	22 (18.8%)	95 (81.2%)	1.55
Constipation	10 (8.5%)	9 (7.7%)	1 (<1.0%)	20 (17.1%)	97 (82.9%)	1.55
Weakness	13 (11.1%)	13 (11.1%)	3 (2.6%)	29 (24.8%)	88 (75.2%)	1.66

the higher the score, the higher the severity. Fatigue (65.8%, n=77) was the most frequently reported symptom. Of those reporting the presence of fatigue, forty-five (38.5%) reported mild fatigue, twenty-six (22.2%) reported moderate fatigue and six (5.1%) reported severe fatigue. The average severity among those reporting the presence of fatigue was 1.49.

Pain (39%) was the second most frequently reported symptom present in the eight week period following breast cancer surgery. Among those reporting the presence of pain, 29 (24.8%) reported mild pain, sixteen (13.7%) reported moderate pain, and one (<1%) reported severe pain. The average severity among those reporting pain was 1.39, between mild and moderate.

Trouble sleeping (35%, n=41) ranked as the third most prevalent of the symptoms reported. Sixteen subjects (13.7%) reported mild trouble sleeping, 19 (16.2%) reported moderate trouble sleeping and 6 (5.1%) reported severe trouble sleeping. Although trouble sleeping was the third in terms of numbers of subjects reporting the symptom, trouble sleeping scored the highest (1.76, between mild and moderate) for the average severity of the symptom. The presence of other symptoms such as weakness (24.8%), poor appetite (18.8%), constipation (17.2%), and nausea (14.5%) were reported to lesser extent respectively.

Functional limitations of the sample are reported in Table 3. The severity of the limitations were ranked from one to three with the lower the score, the more limitation. Limitation of vigorous activities such as lifting heavy objects, participating in strenuous sports (76.3%) was the most reported limitation. Of those with limitations of vigorous activities, 48 (42.1%) reported a lot of limitation and 39 (34.2%) reported a little limitation. The average severity of limitation was 1.45, midway between limited a little and limited a lot.

The second most frequently reported limitation (54.6%) was the ability to walk more than one mile. Forty (36.4%) subjects reported a lot of limitation and 25 (18.2%) reported a little limitation. Limitation in the ability to walk more than one mile was scored as the most severe limitation (1.33).

Table 3.

Summary of Responses to Functional Ability Items Within Eight Weeks of Surgery

Symptoms	Yes, limited a lot=1	Yes, limited a little=2	Total Limitations	No, not limited at all=3	Average limitation for those reporting any level of limitation	Missing Data	n
Moderate activities such as moving a table, bowling, or playing golf	28 (24.1%)	30 (25.9%)	58 (50%)	58 (50.0%)	1.52	1	116
Vigorous activities such as lifting heavy objects, participating in strenuous sports	48 (42.1%)	39 (34.2%)	87 (76.3%)	27 (23.7%)	1.45	3	114
Lifting or carrying groceries	17 (14.9%)	35 (30.7%)	52 (45.6%)	62 (54.4%)	1.67	3	114
Climbing several flights of stairs	20 (17.4%)	27 (23.5%)	47 (40.9%)	68 (59.1%)	1.57	2	115
Climbing one flight of stairs	8 (6.9%)	14 (12.1%)	22 (19%)	94 (81%)	1.64	1	116
Bending, kneeling or stooping	21 (18.0%)	33 (28.2%)	54 (46.2%)	63 (53.8%)	1.61	0	117
Walking more than one mile	40 (36.4%)	20 (18.2%)	60 (54.6%)	50 (45.4%)	1.33	7	110
Walking several blocks	21 (18.1%)	25 (21.6%)	46 (39.7%)	70 (60.3%)	1.54	1	116
Walking one block	11 (9.4%)	15 (12.8%)	26 (22.2%)	91 (77.8%)	1.58	0	117

Limitation in moderate activities such as moving a table, bowling, or playing golf was reported by 50% of the subjects. Of those reporting this limitation, 28 (24.1%) of the subjects reported a lot of limitation and 30 (25.9%) reported a little limitation. The average severity was 1.5, midway between limited a little and limited a lot.

Research question number one was further answered by computing correlation coefficients to describe the relationship between pain and other symptoms (Table 4) and physical limitations (Table 5). Pain was operationalized as a score on the Symptom Experience Index. Trouble sleeping (r=.27, p=.003) and poor appetite (r=.19, p=.035) were correlated significantly with pain. None of the functional ability limitations correlated significantly with pain. As expected, a negative correlation exists between pain (for which a higher score reflects more pain) and the physical limitation items (for which a higher score means fewer limitations), even though the relationships were not found to be statistically significant.

The functional ability limitations reported by patients were those that may impact routine daily activities and roles. Moderate activities include activities like preparing meals and doing dishes. A limitation in the ability to lift or carry groceries, as reported by 52 subjects (45.6%), may impact the woman's perception of the role of wife and grandmother. Lifting is involved in grocery shopping, a function many wives in this age group

Table 4.

Pairwise Correlations Among the Presence of Pain and the Presence of Other Symptoms (n=117)

	Pain	Nausea	Fatigue	Trouble Sleeping	Poor Appetite	Constipation	Weakness
Pain							
Nausea	.1150 p=.217						
Fatigue	.0637 p=.495	.0415 p=.657					
Trouble Sleeping	.2731 p=.003*	.1971 p=.033*	.2389 p=.009*				
Poor Appetite	.1948 p=.035*	.2361 p=0.10*	.1163 p=.212	.3695 p=.000*			
Constipation	.1150 p=.217	.0600 p=.521	.1962 p=.034*	.0679 p=.467	.1739 p=.061		
Weakness	.0637 p=.495	.1565 p=.092	.2468 p=.007*	.2307 p=.012*	.2304 p=.012*	.1442 p=.121	

see as their role. Lifting limitations also affect the ability to show affection to small grandchildren by holding them.

Research Question #2

To answer research question number two: Is there a difference in the relationship between pain and physical well-being by sociodemographic factors, a series of chi square (X^2) analyses were computed. Chi square analyses were computed to test the significance of differences of proportions in categories within the sociodemographic variables. The sociodemographic variables of age, education, household members and current work situation were chosen for chi square analyses as there was adequate data

Table 5.

Pairwise Correlations Among the Presence of Pain and the Presence of Physical Limitations (n=117)

	V_1	V_2	V_3	V_4	V_5	V_6	V_7	V_8	V_9	V_9
V_1										
V_2	-.1694 *p*=.069									
V_3	-.0614 *p*=.513	.3907 *p*=.000								
V_4	-.1358 *p*=.146	.3654 *p*=.000*	.1048 *p*=.263							
V_5	-.1073 *p*=.252	.1062 *p*=.257	.0593 *p*=.527	.2994 *p*=.000*						
V_6	.0275 *p*=.769	.2332 *p*=.012*	.0755 *p*=.421	.4733 *p*=.000*	.5056 *p*=.000*					
V_7	-.1257 *p*=.177	.1518 *p*=.104	.1199 *p*=.200	.2393 *p*=.010*	.3176 *p*=.001*	.3288 *p*=.000*				
V_8	-.0675 *p*=.470	.1739 *p*=.062	.0781 *p*=.405	.2901 *p*=.002*	.4218 *p*=.000	.5044 *p*=.000	.2677 *p*=.004 *			
V_9	.0002 *p*=.998	.2093 *p*=.025*	.1991 *p*=.033*	.3574 *p*=.000*	.4925 *p*=.000*	.4745 *p*=.000*	.3057 *p*=.001 *	.6659 *p*=.000 *		
V_{10}	-.0825 *p*=.392	.2669 *p*=.005*	.2584 *p*=.007*	.2959 *p*=.002*	.3841 *p*=.000*	.3381 *p*=.000*	.3032 *p*=.001 *	.3471 *p*=.000 *	.7046 *p*=.000 *	

available and it was hypothesized that there may be proportionate differences.

Age by Symptom Frequency and Functional Ability

It is important to note when interpreting this analysis that there were 76 women in 65-74 year age group and 40 women in the 75+ age group. The results of X^2 analyses for age by symptom frequency were statistically significant (X^2 significant, *p*<.05) for only the symptom of poor appetite (*p*=.03). There was a difference in proportions of people who experienced poor appetite between age group 65-74 years (13.2%) and age group 75+ years (30%) in that study participants in the group age 75+ years reported a higher proportion of poor appetite.

There were no statistically significant results for age by functional limitations, although the X^2 for the limitation of walking more than one mile approached statistical significance ($p=.05091$). There was some difference in the proportions of people who experienced the limitation of walking more than one mile between age group 65-74 years (48.6%) and age group 75+ years (68.6%). Perhaps if the sample sizes for age groups had been similar, the results would have been different. The smaller numbers of patients in the age group 75+ may have skewed the data to reflect that more limitations were present in this age group. For instance, in the age group, 75+, there were almost 50% fewer participants in the group than in the age group 65-74 years.

Patient Education by Symptom Frequency and Functional Ability

Chi square analyses for patient education by symptom frequency were statistically non-significant. Patient education by functional ability computed statistically significant (X^2 significant, $p<.05$) only for the limitation climbing one flight of stairs ($p=.01003$).

Living Arrangement by Symptom Frequency and Functional Ability

There was a difference in proportions of women who experienced weakness between the Living Alone group (34.1%) and the group Living with Another (12.9%). One explanation for this finding is that those living alone feel weaker because they are caring for themselves while those living with another person may have less weakness because they are receiving help from those living with them.

Household members by functional ability limitation computed statistically significant (X^2 significant, p=.04712). There was a difference in proportions of women who experienced any limitation between the group Living Alone (64.9%) and the group Living With Someone (44.1%). Women living alone reported more functional limitations than did those living with someels. An explanation of this may be that those women living alone had to perform or attempt to perform functions that those women living with someone may not have had to do, such as functions necessary to prepare meals and other household chores.

Current Work Situation by Symptom Frequency and Functional Ability

The results of chi square analyses for current work situation by symptom frequency and physical limitations were statistically non-significant. There were no differences in proportions of women for symptom frequency or physical limitations between the group employed and the group not employed. As would be expected for the sample age group, the employed group (n=36) was much smaller than the not employed group (n=81).

In summary, the sociodemographic characteristics of patient age, education, current work situation and household members were generally not associated with the relationship between pain and symptoms and functional ability, except for the several exceptions described.

Chi square analyses were chosen because the Chi square statistic can be applied to contingency tables to test the significance of different proportions with groups. The advantage of Chi square tests for the study is that as a non-parametric statistic, rigorous assumptions regarding the distribution of the critical variables were no required. The study was secondary data analysis and the demographic characteristics were nominal and ordinal level data. The disadvantage of the Chi square statistic is that it does not analyze variance within the sample groups.

SUMMARY AND IMPLICATIONS

Limitations of the Study

Limitations of this study may have affected the significance of the variable relationships or the ability to generalize the findings to a larger population. Only selected symptoms from the Symptom Experience tool were studied as to their affect on the quality of life domain of physical well-being. This tool has not been widely used and additional research using subsets of the tool in a wider variety of populations would be appropriate.

A convenience sample was obtained by recruiting participants from twenty-three community hospitals affiliated with Michigan State University. The sample was essentially Caucasian. Future studies should address a more ethnically diverse population and other under-served or at-risk populations.

Functional limitations and presence of symptoms were generally not associated with demographic factors such as age, household members, education and work situation. Further study to determine whether these variables may impact symptoms and functional limitation is needed..

This study did not include the analysis of pre-operative assessment of symptoms and functional ability. Thus, there was not a method to identify how much of the perceived post-operative symptom distress and functional ability were carry-overs from pre-operative morbidities.

Unfortunately, the study sample lacked ethnic diversity. Any attempt to develop protocols or care plans to address either problems related to symptom management or physical functioning in the post-operative period should take into account the needs of our culturally and ethnically divers populations. In developing plans that involve social support, it is important to note that African-American and Mexican American cultures have elements of cultural uniqueness in terms of support and expression of symptoms and illness (Jackson, Neighbors & Gurin, 1986; Giger & Davidhizar, 1991).

Implications for Advanced Nursing Practice

Implications for advanced practice nursing in the areas of clinical practice, education and research were evident from the study.

The symptom of fatigue was present in 65.8% of the study participants (n=77) with an average severity of mild to moderate among people who reported any level of fatigue. The nurse in advanced practice, in the role of teacher/ coach, can collaborate with the patient to develop plans and to provide anticipatory guidance to minimize fatigue in the post-operative period.

Post-operative pain (39.5%, n=46) was also reported to be a prevalent symptom within the eight weeks of hospital discharge following breast cancer surgery among study participants with an average severity of mild to moderate pain among those reporting any level of pain. Trouble sleeping (35%, n=41) and weakness (24.8%, n=29) were also perceived to be prevalent symptoms during the post-operative period. The symptoms moderately to strongly correlate with each other and if one or more symptoms were controlled, perhaps others would then be controlled as well. The control of symptoms would then, as described in the conceptual model, increase the patients' quality of life and decrease costs. Part of nursing's role is to examine how inadequate symptom management impacts the use and cost of services by increasing numbers of encounters for health care services.

Perioperative patient education regarding post-operative fatigue, pain management, sleeping and eating, and, the inter-relatedness of these symptoms is necessary. Older women following surgery for breast cancer need to be taught to notify the health care provider (specifically who and when) if medications taken as prescribed do not alleviate the pain or cause other symptoms such as trouble sleeping or constipation. To assist in preventing pain or discomfort and trouble sleeping, post-operative patients should be taught to elevate the operative aim and hand by supporting it on the back of a chair or sofa and to position self while lying so the operative side is up and not dependent to reduce the effect of lymphedema and surgical site tension and resulting discomfort. To further promote relaxation and improve trouble sleeping, women should be taught how to institute non-pharmacological interventions such as imagery and jaw relaxation techniques (McCaffery & Beebe, 1989).

Seventy-six percent (n=87) of the subjects reported limitations performing vigorous activities (average limitation between limited a little and limited a lot), 54.6% (n=58) reporting limitations walking more than one mile (average limitation between limited a little and limited a lot). Information regarding the functional limitations of the elderly post-operatively and the need to assess whether the patient can function when returned home are important based on the results of this study regarding the amount of physical limitation found post-operatively in the sample. Although it may not be expected that elderly women would need to walk more than a mile or perform vigorous activities in the post-operative period, the inability to perform them may impact the woman's perception of quality of life. For instance, vigorous activities include lifting heavy objects; lifting a grandchild for hugs may fall into this category. This information is important to the advanced practice nurse, as case manager, in assuring that the patient can return home and function safely.

The advanced practice nurse will need to draw on his/her skills and background to provide case management for elderly women with breast cancer post-operatively to coordinate services among providers (primary care, oncologist, surgeon), payers and significant others to assure symptom management and functional abilities are maximized.

Implications for nursing education include the need to provide instruction to undergraduate and graduate nurses regarding physical functioning and symptom management post-operatively in elderly women having breast cancer surgery procedures. Nurses must be taught to both assess, educate and intervene for the patient regarding post-operative fatigue. Measures to minimize fatigue and improve the patients' perceptions of quality of life are important to the patients' overall healing process.

Nursing education must also focus on pain management techniques and factors that may impede pain management from the perspective of patients and practitioners. Nursing has historically focused on care in acute care facilities, particularly hospitals. As patients are discharged from hospitals more quickly and care is shifting to community-based or home-based care, nursing must respond by assuring that nurses are able to identify unique circumstances in the home environment that may impede symptom management and/or physical abilities.

There are several implications for nursing research gleaned from this study. Jacox (1992) suggests that the problem of poor pain management is due primarily to the lack of well-controlled clinical studies of methods of pain management and the lack of use by practitioners of what is known about pain management. The nurse in advanced practice can provide information to nurses, physicians and other health care providers regarding methods of pain control and assist in research why others do not implement methods of pain management that are known.

The study needs to be replicated with a population that is more ethnically and socially diverse in order to make inference about the impact of pain on physical well-being and quality of life to the larger population. Future studies should also account for disease stage, type of breast procedure performed, analgesics prescribed and other treatment modalities such as radiation therapy and chemotherapy which impact symptoms and functional limitations. The study was not able to study relationship or impact of income and marital status on pain and physical well-being; these should be considered in future studies. Further research should also be undertaken to study the impact of preoperative teaching and anticipatory guidance on post-operative outcomes of symptom distress and physical limitations.

Summary

In summary, patients' perceived the presence of symptoms and physical limitations within the first eight weeks of hospital discharge following breast cancer surgery procedures. Although this study did conclude that pain directly impacted the symptoms of appetite and sleep and vigorous activities of the participants, the presence of other symptoms and functional ability limitations presents challenges for the nurse in advance practice. This study pointed out the disappointing fact of the pervasive presence of symptoms and physical limitations in the post-operative period for elderly women following breast cancer surgery procedures and our seeming inability to manage them.

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APPENDIX A

DEMOGRAPHICS INSTRUMENT

Circle if: SHORTENED

cs:W1PTNOCG.INT
4/25/96

WAVE I

PATIENT WITHOUT CAREGIVER TELEPHONE INTERVIEW

"Family Home Care for Cancer – A Community-Based Model"

Grant #2 R01 NR/CA01915
Funded by the National Institute of Nursing Research and the National Cancer Institute
Barbara A. Given, PhD, RN, FAAN, and Charles W. Given, PhD, Co-Principal Investigators

NINR/NCI SCREENING

ID __ __ __ __/INT __
DATE __ __/__ __/__ __

SCREENING CANCER PATIENT
NAME AND ADDRESS from Pre-Enrollment Form

1. Name of Patient: ______________________________
2. Address of Patient: ______________________________
____
____
3. Telephone: (____)________________________
4. Name and phone number of contact person if unable to reach patient:

Name: ______________________________
Relation to patient: ______________________________
Telephone: (____)________________________
Location: ______________________________
____

Attempts to contact patient (date and time).

________________ ________________ ________________
________________ ________________ ________________

NINR/NCI SCREENING

ID __ __ __ __/INT __
DATE __ __/__ __/__ __

Introduction:

"Hello, my name is ________________________. I am a project staff member for the Family Care Study at Michigan State University. Recently we sent you information about the study and you signed a consent form and sent it back to us."

"The questions I would like to ask you will take approximately 45 minutes to an hour. Is now a good time for you to answer these questions or would you like to schedule another time, or perhaps, I could ask some of the questions now and schedule another time to finish? Whatever is most convenient for you. Would you like to try some now?"

Interviewer: Set up appointment for interview:

__________ Day
__________ Time

Interviewer: Some of the participants need to be reminded of the amount of time and involvement that this study will require of them.

1. Only telephone conversations, although there may be home visits for special circumstances.
2. Can withdraw from study at any time.
3. Can always contact us for information, at (517) 353-3843 ext 433 (Keely Englesby), or 1-800-654-8219.
4. Interviewer will contact participant by telephone to set up appointment at participant's convenience. Self-administered questionnaire will then be mailed to allow at least one week for patient to fill out.

Interviewer: If patient DOES want to participate:

"We appreciate your willingness to participate. I would like to remind you that all information will be held in the strictest confidence and will not be linked to you as an individual in any way. This information is necessary to describe the situations of individuals with cancer as a group to try to identify needed resources."

Interviewer: If patient DOES NOT want to participate:

"Would you be willing to let us know what your reasons are for not participating in the study at this time?"

Reasons for not participating: ______________________________

____

"At this time, we will not plan to contact you again. If for any reason you change your mind and decide that you would like to participate, feel free to call us. Do you have our number?"

"Thank you for your time."

NINR/NCI WAVE I PATIENT W/O CAREGIVER TELEPHONE

ID __ __ __ __/INT __
DATE __ __/__ __/__ __

Prior to interview- Enter date (month, day and year) and interviewer number on each page, if indicated.

SOCIODEMOGRAPHIC INFORMATION FOR CANCER PATIENT

1. Sex of patient: (check one) ____ Male (1) ____ Female (2)

2. What is your birthdate? (write in)

___/___/___
Month/ Day /Year

3. What is your highest level of education completed? (check one)

_____ No formal education (1)
_____ Completed grade school (2)
_____ Completed some high school (3)
_____ Completed high school (4)
_____ Completed some college or technical training (5)
_____ Completed college (6)
_____ Completed graduate/professional degree (post baccalaureate degree) (7)
_____ NA/Refused (9)

4. What is your race or ethnic background? (check one)

_____ Caucasian/White (1)
_____ African American/Black (2)
_____ Mexican American/Hispanic/Chicano (3)
_____ Native American/Alaskan (4)
_____ Oriental/Asian/Pacific Islander (5)
_____ Other (6) (specify ____________________________)
_____ NA/Refused (9)

5. What is your marital status? (check one)

______ Never married (1)
______ Married (2)
______ Divorced/Separated (3)
______ Widowed (4)
______ NA/Refused (9)

(GO TO NEXT PAGE)

ID ___ ___ ___ ___/INT ___
DATE ___ ___/___ ___/___ ___

6. In which county do you live?

____
(write in county)

_____ NA/Refused

7. When was the month and year you moved to this county? (write in)

_____/_____
Month/Year

Now we are going to ask you questions about who lives with you, and about persons who might help you.

8. Who lives in your household with you? (check all that apply)

___ No one - lives alone (1)
___ Spouse (2)
___ Other (3)
___ NA/Refused (9)

9. Do any children live with you?

___ Yes (Go to 9a)
___ No (Go to 10)
___ NA/Refused

9a. If Yes was checked, then:

(a9A) How many children under 13 years of age?
_____(write in number)

(b9A) How many 13 to 17 years of age?
_____ (write in number)

(c9A) How many 18 years or older?
_____ (write in number)

9b. ___ Any other children under 18 years of age (4)

(a9B) How many children under 13 years of age?
_____(write in number)

(b9B) How many 13 to 17 years of age?
_____ (write in number)

(GO TO NEXT PAGE)

9c. ___ Adult relatives other than your children (18 years or older) (5)

(a9C) How many adult relatives?
_____(write in number)

9d. ___ Other unrelated adults (18 years or older) (6)

(a9D) How many unrelated adults?
_____(write in number)

9e. ___ NA/Refused (9)

(Interviewer: Step-daughter, -son; check as daughter, son.)

10. **Is there someone who helps you with care of any type, including bathing, dressing, medications, or even transportation? (check one)**

___ Yes (1)
___ No (2) (If NO, go to question 11)
___ NA/Refused (9)

10a. If YES, who helps you? (Indicate relationship <u>to</u> patient, including step-children, e.g., if a daughter is helping her mother, check daughter) (check as many as apply)

___ Wife (1)
___ Husband (2)
___ Daughter (3)
___ Son (4)
___ Daughter-in-law (5)
___ Son-in-law (6)
___ Sister/sister-in-law (7)
___ Brother/brother-in-law (8)
___ Mother (9)
___ Father (10)
___ Aunt (11)
___ Uncle (12)
___ Niece (13)
___ Nephew (14)
___ Granddaughter (15)
___ Grandson (16)
___ Other (please specify ________________________) (17)
___ NA/Refused (99)

10b. From among all the persons you have indicated that may help you, which one person helps the most or is most willing to help should the need arise? (write in)

Name of person and relationship: ________________________________

(GO TO NEXT PAGE)

ID ___ ___ ___ ___/INT ___
DATE ___ ___/___ ___/___ ___

Note: We will refer to this person as your PRIMARY CAREGIVER.

10c. Does your primary caregiver live with you? (check one)

___ Yes (Go to question 11) (1)
___ No (Go to question 10d) (2)
___ NA/Refused (9)

10d.

Interviewer: If not spouse, then get mailing address and telephone number of primary caregiver:

Name: ____________________

Address: ____________________

City: __________ State: __________ Zip: ______

Telephone: (____)____________________

Is this person paid by you, or is anyone paid to assist you?

_____ Yes _____ No

If yes, what is the weekly/monthly wage? $__________

11. Because of the need for assistance with cancer, did ... (check one)

_____ You move to caregiver's home (Go to question 11a) (1)
_____ Caregiver move into your home (Go to 11a) (2)
_____ You move closer to caregiver (Go to 11a) (3)
_____ Caregiver move closer to you (Go to 11a) (4)
_____ You move to a facility that provides care (Go to 11a) (5)
Please describe facility: ____________________
____
_____ No one move (Go to question 12) (6)
_____ NA/Refused (9)

11a. If movement occurred, what was the month and year of movement? (write in)

_____/_____
Month/Year

_____ NA/Refused (9)

(GO TO NEXT PAGE)

APPENDIX B

MEDICAL OUTCOMES STUDY - FS36

ID __ - __ __/INT __
DATE __ __/__ __/__ __

INSTRUMENTAL ACTIVITIES OF DAILY LIVING FOR THE PATIENT

I. The following questions are about the activities you might do during a typical day. First, I'll ask you about performing these activities 3 or more months ago, or before you were diagnosed with cancer, and then I'll ask you about these activities currently. Does your health limit your ability to do activities? If so, how much? (Circle one for each question — 3 months ago and currently.) (Interviewer: Thinking back to date three months ago were you limited in ... because of your health? What about now? We are interested in your ability to do these activities.)	Three months ago, or before you were diagnosed with cancer, did your health limit you in these activities?			Currently does your health now limit you in these activities?		
	Yes, Limited A Lot (3)	Yes, Limited A Little (2)	No, Not Limited At All (1)	Yes, Limited A Lot (3)	Yes, Limited A Little (2)	No, Not Limited At All (1)
ı. Moderate activities, such as moving a table, bowling, or playing golf?	3	2	1	3	2	1
›. Vigorous activities, such as lifting heavy objects, participating in strenuous sports?	3	2	1	3	2	1
:. Lifting or carrying groceries?	3	2	1	3	2	1
I. Climbing several flights of stairs?	3	2	1	3	2	1
ı. Climbing one flight of stairs?	3	2	1	3	2	1
. Bending, kneeling, or stooping?	3	2	1	3	2	1
ı. Walking more than a mile?	3	2	1	3	2	1
ı. Walking several blocks?	3	2	1	3	2	1
Walking one block?	3	2	1	3	2	1

NINH/NCI W PATIENT W/O CAREGIVER TELEPHONE

ID __ - ____/INT __
DATE __ __/__ __/__ __

The next few questions will ask only about your current condition.

2. How much overall physical pain have you had during the past four weeks? (circle one)	None (1)	Very Mild (2)	Mild (3)	Moderate (4)	Severe (5)	Very Severe (6)

3. During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (circle one)	Not at All (1)	Slightly (2)	Moderately (3)	Quite a Bit (4)	Extremely (5)

(GO TO NEXT PAGE)

APPENDIX C

SYMPTOM EXPERIENCE INDEX

NINR/NCI W▸ PATIENT W/O CAREGIVER TELEPHONE

ID _ _ _ _/INT __
DATE _ _/_ _/_ _

PATIENT SYMPTOM EXPERIENCE

The following is a list of symptoms that <u>some</u> people with cancer experience either from the illness or as a result of treatment.
If you have not experienced the symptom <u>in the past two weeks</u>, answer NO.
If you have experienced the symptom <u>in the past two weeks</u>, answer YES, then identify how severe this symptom was, indicating the severity of this symptom, either 1 = MILD, 2 = MODERATE, or 3 = SEVERE.
Finally, we will ask you to identify the extent this symptom has caused you to limit your regular activity, either 1 = NO EXTENT, 2 = SMALL EXTENT, 3 = SOME EXTENT, 4 = GREAT EXTENT, or 5 = VERY GREAT EXTENT.

We appreciate your helping us understand the impact of any symptom you may experience.

(Leave any category blank in columns B & C if symptom not experienced.)

	A. Did you experience this symptom in the <u>past two weeks</u>? (circle one)		B. If yes, how severe is this symptom for you? (circle one if experienced)			C. To what extent has this symptom disrupted or caused you to limit your regular daily activities? (circle one)				
SYMPTOMS	YES (1)	NO (2)	MILD (1)	MODERATE (2)	SEVERE (3)	NO EXTENT (1)	SMALL EXTENT (2)	SOME EXTENT (3)	GREAT EXTENT (4)	VERY GREAT EXTENT (5)
1. Nausea.	1	2	1	2	3	1	2	3	4	5
2. Pain.	1	2	1	2	3	1	2	3	4	5
3. Trouble sleeping.	1	2	1	2	3	1	2	3	4	5
4. Fatigue.	1	2	1	2	3	1	2	3	4	5
5. Difficulty breathing/ shortness of breath.	1	2	1	2	3	1	2	3	4	5
6. Diarrhea.	1	2	1	2	3	1	2	3	4	5
7. Coordination problems.	1	2	1	2	3	1	2	3	4	5
8. Vomiting.	1	2	1	2	3	1	2	3	4	5

NINR/NCI WA PATIENT W/O CAREGIVER TELEPHONE

ID _ _ _ _/INT __
DATE _ _/_ _/_ _

(Leave any category blank in columns B & C if symptom not experienced.)

	A. Did you experience this symptom in the <u>past two weeks</u>? (circle one)		B. If yes, how severe is this symptom for you? (circle one if experienced)			C. To what extent has this symptom disrupted or caused you to limit your regular daily activities? (circle one)				
SYMPTOMS	YES (1)	NO (2)	MILD (1)	MODERATE (2)	SEVERE (3)	NO EXTENT (1)	SMALL EXTENT (2)	SOME EXTENT (3)	GREAT EXTENT (4)	VERY GREAT EXTENT (5)
9. Difficulty concentrating.	1	2	1	2	3	1	2	3	4	5
10. Weakness.	1	2	1	2	3	1	2	3	4	5
11. Dizziness.	1	2	1	2	3	1	2	3	4	5
12. Numbness, tingling, loss of feeling.	1	2	1	2	3	1	2	3	4	5
13. Poor appetite. ✓	1	2	1	2	3	1	2	3	4	5
14. Weight loss.	1	2	1	2	3	1	2	3	4	5
15. Fever.	1	2	1	2	3	1	2	3	4	5
16. Cough.	1	2	1	2	3	1	2	3	4	5
17. Dry mouth.	1	2	1	2	3	1	2	3	4	5
18. Constipation. ✓	1	2	1	2	3	1	2	3	4	5
19. Frequent urination.	1	2	1	2	3	1	2	3	4	5
20. Dehydration.	1	2	1	2	3	1	2	3	4	5
21. Mouth sores.	1	2	1	2	3	1	2	3	4	5

APPENDIX D

UCRIHS APPROVAL

MICHIGAN STATE
UNIVERSITY

February 26, 1996

TO: Evelyn Bochenek
3213 West Holt Road
Mason, MI 48854

RE:
IRB#: 96-110
TITLE: FEMALE BREAST CANCER PATIENTS' PERCEPTIONS OF PAIN AND PHYSICAL WELL-BEING FOLLOWING MASTECTOMY FOR BREAST CANCER
REVISION REQUESTED: N/A
CATEGORY: 1-E
APPROVAL DATE: 02/26/96

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Sincerely,

David E. Wright, Ph.D.
UCRIHS Chair

DEW:bed

cc: Barbara A. Given

OFFICE OF
RESEARCH
AND
GRADUATE
STUDIES

University Committee on
Research Involving
Human Subjects
(UCRIHS)

Michigan State University
232 Administration Building
East Lansing, Michigan
48824-1046

517/355-2180
FAX: 517/432-1171

APPENDIX E

UCRIHS APPROVAL FOR LONGITUDINAL STUDY

MICHIGAN STATE
UNIVERSITY

June 6, 1995

TO: Barbara A. Given
A230 Life Sciences

RE: **IRB#:** 92-280
TITLE: FAMILY HOME CARE FOR CANCER--A COMMUNITY-BASED MODEL
REVISION REQUESTED: 05/25/95
CATEGORY: FULL REVIEW
APPROVAL DATE: 06/05/95

The University Committee on Research Involving Human Subjects'(UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Sincerely,

David E. Wright, Ph.D.
UCRIHS Chair

DEW:kaa/lcp

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