Title

Assessing breast cancer patients' self-care behaviors for nausea and vomiting from chemotherapy

Author

Luo, Li-Hua,

Publication Date

1988

Peer reviewed|Thesis/dissertation

Assessing Breast Cancer Patients' Self-Care Behaviors

for Nausea and Vomiting from Chemotherapy

by

Li - Hua Lo

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

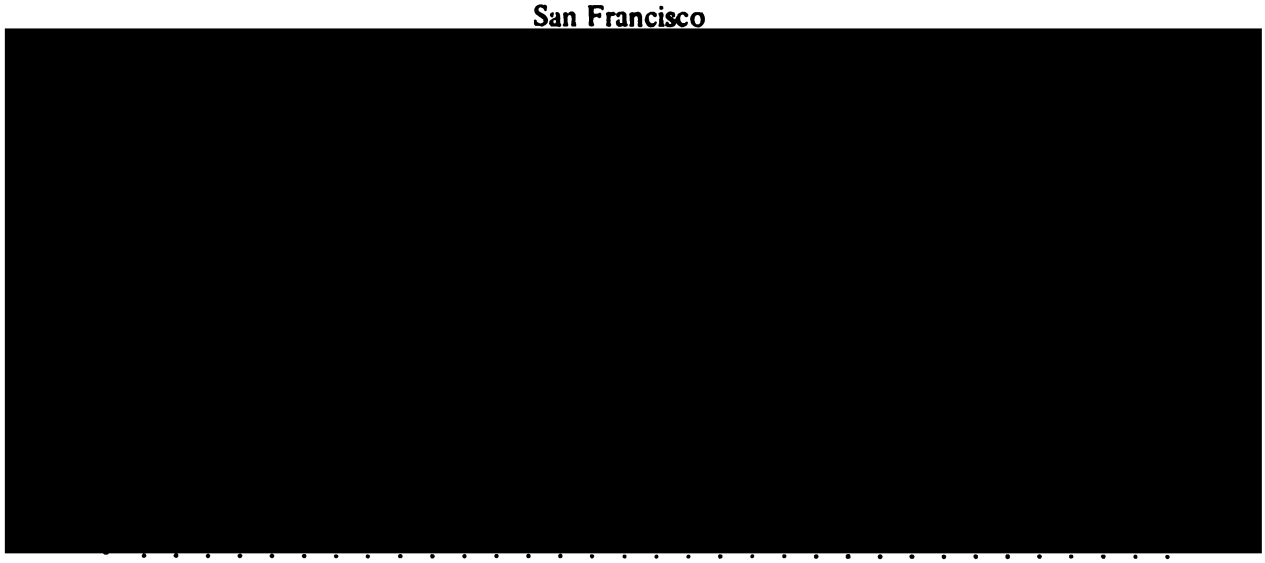
in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA

San Francisco



Date **University Librarian**

Degree Conferred: JUL 12 1988

Assessing Breast Cancer Patients' Self-Care Behaviors for Nausea and Vomiting from Chemotherapy

Li-Hua Lo

Abstract

The purpose of this study, which used a descriptive longitudinal research design, was to identify the self-care behaviors (SCBs) of two groups of outpatients with breast cancer who experienced nausea and vomiting (NV) as a result of chemotherapy. Group A patients received cycle 1 chemotherapy and Group B received cycle two to six chemotherapy. Each group has six patients in this study. Data were collected prior to and at 12-hour intervals after chemotherapy was administered, for 72 hours (there were seven data collection periods, Time 1 to Time 7). At each data collection period, a combination of the following instruments was used: (a) a Demographic Data Inventory, (b) the Spielberger State-Trait Anxiety Inventory (STAI), (c) an adapted version of Rhodes Index of Nausea and Vomiting Scale (RINV), (d) an adapted version of Dodd's Self-Care Behavior Log (SCBL). Data analysis was conducted by the Crunch software statistical package, using descriptive and non-parametric statistics and Spearman's correlations. The findings of this study corroborated the results of Dodd and Rhodes. The reported average SCBs for NV in breast cancer patients was 1.21 (SD = 1.35); the SCB efficacy ratio was 1.68 (SD = 2.22) on a 5-point scale. Chemotherapy-induced

NV were found to be different concepts. No significant differences between Group A and B on the four SCB ratios. The results emphasizes the need to replicate the study in a larger sample size in order to establish the patterns of SCBs for NV in breast cancer patients receiving chemotherapy.

Acknowledgments

I wish to thank the patients who participate in this study. I appreciated their cooperation and contribution to my study.

I thank the nurses, physicians and clerical staff in Chang Gung Memorial Hospital for their support.

I acknowledge the members of my thesis committee: Marylin J. Dodd, RN, Ph.D., FAAN (chairperson), Nancy Lovejoy, RN, D.S.N., and Ida Marie (Ki) Moore, RN, D.N.S. for their support. I really appreciate their guidance and assistance to help me work through the entire research process in this area during these two years.

I acknowledge Steven Paul, Biostatistician, for his consultation in the analysis of my data.

I acknowledge Marylin J. Dodd, Verna A. Rhodes, and Charles D. Spielberger for allowing me to use and modify their instruments. Without their courtesy, this study might never have taken place.

I acknowledge Annemarie Kesselring and Jim Grout for editing and giving me some suggestions.

I also wish to acknowledge the Association of Nursing, R.O.C. and my friends and family, who encouraged and supported me throughout my graduate education.

Table of Contents

List of Tables

List of Figures

List of Appendices

CHAPTER ONE

Introduction

Nausea and vomiting (NV) were the stressful side effects of chemotherapy identified most commonly by both oncology nurses (83%) and patients with cancer (71%) (Kennedy, Packard, Grant, & Padilla, 1981). Clinical observations also have shown that for some patients with cancer the side effects of treatment seemed worse than the disease itself (Cotanch, 1984; Lindsey, 1985; Oberst, 1978; Rhodes, Watson, & Johnson, 1984). Severe NV may result in extreme patient discomfort and become the source of patient refusal of further courses of chemotherapy. In some cases, patients have actually refused potential curative therapy because of NV (Laszlo, 1983).

Chemotherapy is a common prescribed treatment modality in many types of cancer, particularly breast cancer. Because of the relatively high incidence of breast cancer, chemotherapy-induced NV is experienced by a sizeable portion of the cancer population.

According to the American Cancer Society's report (1987, 1988), breast cancer will occur in 1 of every 10 females in the United States at sometime in their lives, and accounts for 27% of all cancer in females. The annual mortality rate of 27 per 100,000 females has remained essentially unchanged for 50 years. It accounts for 18% of

cancer deaths in females. Based on the report of Department of Health, the Executive Yuan, Taiwan, R.O.C. (1985), breast cancer was the second leading site of female cancer incidence in Taiwan following cervical cancer. The crude incidence rate of breast cancer was 9 per 100,000 females in Taiwan.

Adjuvant chemotherapy has delayed recurrence and improved survival in some patients and Cyclophosphamide, Methotrexate, and 5-Fluorouracil (CMF) have become widely used in adjuvant chemotherapy of primary breast cancer (Bonadonna & Valagussa, 1981; 1985; Henderson & Canellos, 1980; Tancini, Bajetta, Marchini, Valogussa, Bonadonna, & Veronesi, 1979; Wilcox, Fetting, Nettesheim, & Abeloff, 1982). Side effects of the CMF regimen, such as NV, usually occur between 6 and 24 hours after intravenous treatment (Brown, 1987; Keys, Bakemeier, & Savlov, 1983).

The more widely used CMF program yielded a 75% incidence of NV. It was difficult to estimate the number of patients who dropped put of lengthy therapy programs, declined to participate in CMF adjuvant chemotherapy, or had therapy postponed beyond the desirable limits (Laszlo, 1983).

In Johns Hopkins Oncology Center, Wilcox and associates (1982) determined the incidence of post-chemotherapy NV in breast cancer patients receiving CMF adjuvant chemotherapy.

Among 52 patients, post-chemotherapy NV was experienced by 46 (88.5%) and there was a statistically significant relationship between the incidence of severe post-chemotherapy NV and the higher CMF dose ($p < .001$). Severe post-chemotherapy NV (defined as uncontrolled NV interfering with performance of daily activities) occurred in 22 of 52 (42%) patients. Ten of 52 (19%) patients discontinued CMF adjuvant chemotherapy because of NV. Bonadonna and Valagussa (1981) had suggested that the length of the disease-free interval and survival were related to the total dose of CMF administered* (Wilcox et al, 1982). In Meyerowitz and associates' study concluded that almost 50% of women ($N = 35$) treated with CMF did not report a complete return to pre-treatment quality of life four years after mastectomy (Bonadonna & Valagussa, 1985; Meyerowitz, Watkins, & Sparks, 1983).

* Standard-dose CMF -- 100 mg/m2 of Cyclophosphamide orally on Day 1-14, 40 mg/m2 of Methotrexate IV on Day 1 and 8, and 600 mg/m2 of 5-Fluorouracil IV on Day 1 and 8; and Low-dose CMF -- 40 mg/m2 of Cyclophosphamide orally on Day 1-14, 15 mg/m2 of Methotrexate IV on Day 1 and 8, and 350 mg/m2 of 5-fluorouracil IV on Day 1 and 8.

Chemotherapy is given frequently on an outpatient basis over an extended time period (6-12 months), thus patients must assume a major responsibility for their own care and must have sustained motivation to continue the regimen, especially when the treatment produces side effects (Fernsler, 1986). The management of experienced side effects is critically important to prevent and diminish treatment-induced patient morbidity.

Dodd has investigated self-care behaviors (SCBs) in managing the side effects of radiation therapy and chemotherapy in cancer patients (Dodd, 1982a, 1983, 1984a, 1984b, 1984c, 1987, 1988, in press). Rhodes, Watson and Johnson published two studies (1985, 1987) to identify the patterns of NV induced by chemotherapy. However, there has been no documented research specifically focusing on both SCBs and NV in chemotherapy patients. The purpose of this study was partial replication and extension of the studies of Rhodes and Dodd to identify the SCBs for NV episodes in breast cancer patients receiving chemotherapeutic agents on an outpatient basis.

Problem Statement

The successful cancer chemotherapy depends not only upon developing drugs that are effective against specific cancers, but also upon finding methods of reducing the adverse consequences of these drugs. The decreased quality

of life that results from chemotherapy side effects may, in fact, outweigh the increased quantity of life gained from the cancer treatment itself.

To determine the predictors of post-chemotherapy NV for specific antineoplastic drug protocol is imperative. Knowledge of the patterns of frequency, duration, amount, and distress of these two symptoms is essential before developing effective management intervention (Rhodes, et al., 1985).

Several recent nursing research studies (Dodd, 1982a, 1983, 1984a, 1984c, 1988, in press) reported the SCBs of cancer patients receiving chemotherapy, but these did not focus on the specific side effects of NV. The occurrence of NV is notable with cancer chemotherapy. Therefore, assessing cancer patients' SCBs for NV needs to be investigated. The key questions of this study are how breast cancer patients take care of themselves when they experience NV induced by chemotherapeutic drugs, and whether there are significant relationships between the initiation of SCBs and patterns of NV, anxiety level, and demographic variables.

Significance

Nausea and vomiting are the most frequent and distressing treatment related human responses encountered by cancer patients who are receiving chemotherapy. Clinical

observations indicate that for some patients the treatment side effects seem worse than the disease (Lindsey, 1985; Yasko, 1985). Cancer treatment can prolong the quantity of patients' lives, but decrease the quality of their lives. If the patterns of NV can be defined, then the antiemetics can be administered at the most appropriate time. If the SCBs for NV can be determined, then the most effective nursing interventions can be designed and tested to improve the quality of patients' self-care. If some significant relationships between the initiation of SCBs, patterns of NV, and patients' anxiety level can be found, then several hypotheses might be formulated to enlarge nursing knowledge in this area. Since the majority of breast cancer patients receiving chemotherapy are outpatients, they need more capabilities to take care of themselves and nurses can enact an important role in patient teaching. Orem's self-care deficit theory of nursing provides the conceptual framework for this study. This theory will be discussed later.

CHAPTER TWO

Literature Review

Nausea and Vomiting

The relationship between NV is well documented in the literature. In fact, they are almost always mentioned and defined together as one concept. This association is problematic because NV are separate concepts and for clarity need to be defined and treated separately (Borison & McCarthy, 1983; Zook & Yasko, 1983).

In the limited number of references that separate out this concept, nausea has been described as the first of three stages of vomiting: nausea, retching and vomiting. Borison and McCarthy defined nausea as a psychic experience of human beings, accompanied by several autonomic features which help to make nausea measurable. These autonomic features may or may not be associated with vomiting (Borison & McCarthy, 1983).

Vomiting is an objectively quantifiable physiological motor process that can occur without the presence of nausea. The vomiting act consists typically of two phases, namely, retching followed by expulsion. However, retching can happen separately so that no vomitus is expelled. The expulsion phase of vomiting also can occur without preceding retching, in which case this is called projectile vomiting (Borison & McCarthy, 1983; Wyngaarden & Smith, 1982).

However, there are few valid and reliable instruments that measure the patient's perception of nausea and experience of vomiting as separate concepts (Rhodes, Watson, & Johnson, 1984). For the majority of the studies, investigators developed their own "measure" to quantify NV (Cotanch, Hockenberry, & Herman, 1985; Dobkin, Zeichner, & Dickson-Parnell, 1985; Duigon, 1986; Frank, 1985). The availability of valid and reliable outcome measures for NV remains a problem for nursing research. The major problem continues to be accuracy of assessment tools and decreasing the subjectivity associated with measurement (Carey, Burish, & Brenner, 1983; Cotanch, et al., 1985; Lindsey, 1985).

Bryant and Gorton (1982) compared nurses' and physicians' charting of side effects of chemotherapy with cancer patients' perception of toxicity (as recorded on the questionnaire). Patients (n = 30) reported each side effect more frequently than did physicians and nurses. For both groups, the most frequently reported side effect was nausea. Patient self-report of NV may be a more accurate and clinically applicable assessment methodology. It is useful for the quantification of outpatient experiences with self-report of NV (Morrow, 1984).

Patterns of Nausea and Vomiting

Rhodes, Watson and Johnson (1985) described the patterns of NV that occurred during two consecutive cycles

of chemotherapy within the first six months of induction chemotherapy. They used Rhodes Index of Nausea and Vomiting Scale Form 1 (5 items) to measure NV in 32 cancer patients. The findings demonstrated that: (a) patterns of post-chemotherapy nausea are different than patterns of post-chemotherapy vomiting over 72 hours; and (b) there appear to be more individual differences in post-chemotherapy pattern of nausea than in the post-chemotherapy pattern of vomiting. In nearly all cases, the amount and frequency of vomiting were the highest for the first 12 hours following therapy. During the next 12 hours, vomiting amount and frequency were minimal. Within 24 hours following therapy, vomiting ceased. This pattern is a dramatic contrast to the nausea pattern observed. Another finding was the patient's report that nausea frequently persisted for 48 or more hours following administration of the drugs or had a second peak on Day 2 or 3 (Rhodes, et al., 1985). However, this study did not mention the variety of the patients' diagnoses and was limited in a small number of patients who received each drug protocol and not all patients were in the same two cycles that described the relationship between patterns of NV and protocol. This limited generalizability and validity of findings.

Adjuvant chemotherapy may be associated with an anxiety state which appears related to the degree of physical toxicity (Olafsdottir, Sjöden, & Westling, 1986; Welch-McCaffrey, 1985). Meyerowitz, Sparks and Spears (1979) interviewed 50 women receiving adjuvant chemotherapy after surgery for Stage II breast cancer and found 88% of the women reported feeling "sick" and nauseated at least some of the time while on CMF chemotherapy, and half of these women experienced nausea regularly for the entire two weeks of treatment. They also reported a high incidence of anxiety and psychiatric morbidity among breast cancer patients receiving chemotherapy.

Rhodes and associates (1986) designed a study to describe the relationship of anxiety to NV that occurred during consecutive cycles of chemotherapy. The Spielberger's State and Trait Anxiety Inventory (STAI) and Rhodes Index of Nausea and Vomiting Form 2 were administered to 36 adults who were followed for 1-5 consecutive cycles of initial antineoplastic chemotherapy. The results of this study were: (a) State anxiety the morning after chemotherapy was significantly higher than state anxiety prior to chemotherapy for cycle 2 through 5; (b) There were no significant differences in pre-chemotherapy state anxiety scores across three cycles of therapy; (c) There were no significant differences in post-chemotherapy state anxiety

scores across three cycles of therapy; (d) A pattern of positive correlations was found for trait anxiety and pre-chemotherapy state anxiety for cycle 2 through 5; (e) there appear to be protocol specific differences in state anxiety patterns. The findings of this pilot study were also limited by small number of patients who received each drug protocol. The results should not be generalized to other samples. However, these investigators mentioned that there may be few direct relationships between anxiety and NV. Instead, the relationship may be between anxiety and self-care with a secondary relationship between self-care and symptom distress (Rhodes, Watson, & Johnson, 1986).

Rhodes and associates (1987) also published another larger study using self-regulation theory to describe patterns of NV occurrence and distress that emerged during six consecutive cycles of selected initial antineoplastic chemotherapeutic drug regimens. A stratified sample of patients (N = 309), ages 20-84 years, were selected from multiple geographic sites in two mid-western states. The Rhodes Index of Nausea and Vomiting Form 2 was used to measure post-chemotherapy NV. Findings revealed that for 84% of the sample, vomiting was well controlled 48 hours post-chemotherapy, while 71% had little or no nausea. In the remaining sample, three distinct antiemetic drug resistant patterns emerged for each of these dyad symptoms.

There were 43 patients (13.92%), who were receiving CMF antineoplastic drug protocol. Their nausea patterns as Rhodes et al. identified were 40 patients experienced "Minimal Nausea Pattern," two experienced "Latent Nausea Pattern," one experienced "Intense Nausea Pattern" and none experienced "Peak Nausea Pattern." All these patients (n = 43) experienced a "Minimal Vomiting Pattern." No patients experienced "Latent Vomiting Pattern," "Declining Vomiting Pattern" or "Peak Vomiting Pattern" (Rhodes, Watson, Johnson, Madsen, & Beck, 1987).

Palmer (1987) tested the effect of pre-chemotherapy patient education and support on the pattern of NV in 41 cancer patients who were receiving chemotherapy for the first time. A longitudinal experimental design was used to test the efficacy of a patient teaching intervention designed to dispel misconceptions and provide self-care interventions for the control of NV. The subjects received a variety of chemotherapeutic drugs. Data analyses failed to support the hypotheses that patients who received pre-chemotherapy patient education showed a significant reduction in the frequency, duration, amount, and distress of NV attributed to chemotherapy as measured by the Rhodes Index of Nausea and Vomiting and the Adapted Symptom Distress Scale. Additional findings did reveal some difference when considering diagnosis and chemotherapy.

Twenty-one of 41 (51%) patients were diagnosed with breast cancer and it was observed that the nausea, vomiting, and symptom distress experienced by these patients at certain time periods was less than patients with other diagnoses. Also 19 of the 21 breast cancer patients who received CMF chemotherapy, showed significantly less NV and symptom distress during 6-12 hours after chemotherapy than other patients (Palmer, 1987). The pattern of NV in breast cancer patients receiving CMF chemotherapy warrants further research.

Self-Care Behaviors (SCBs)

Kennedy, Packard, Grant, and Padilla (1981) conducted a survey using both nurses (n = 64) and cancer patients (n = 115) as subjects to identify the interventions nurses recommended to prevent or reduce the drug-related NV, and to identify the interventions patients used to relieve NV. Patients and nurses identified antiemetics (53%), distraction (14%), and specific foods (12%) as the three most effective approaches to relieve NV. Patients (40%) reported the time of occurrence of NV as before and immediately following treatment.

Fernsler's descriptive study compared patient and nurse perceptions of patients' self-care deficits associated with cancer chemotherapy in an outpatient setting. An open-ended, semi-structured interview schedule constructed

by the investigator, was used to elicit data from 30 patients and their assigned registered nurses. Subjects' verbatim responses were classified according to the categories of universal self-care requisites developed by Orem (1985, pp.90-91). Of 122 classifiable responses, 75 were from patients and 47 were from nurses. Patients generally perceived more self-care deficits than nurses in the categories that included problems with physical side effects of therapy. The finding in this study that one-fourth of the self-care deficits were associated with food and water supports previous findings that many patients undergoing cancer chemotherapy experience problems with appetite, nausea, and vomiting (Fernsler, 1986).

Dodd has conducted a series of five self-care studies in cancer patients undergoing either chemotherapy or radiation therapy (Dodd, 1982a, 1983, 1984a, 1984b, 1984c, 1987, 1988, in press). The purpose of the first study (Dodd, 1982a, 1983, 1984a) was to determine (a) whether patients ($\underline{N}$ = 48) practice self-care; (b) whether patients instructed in side-effect management techniques (SEMT) would adopt these techniques; and (c) whether information on SEMT, given alone or in combination with other (e.g. drug) information, would enhance self-care activities to manage the experienced side effects of chemotherapy. The patients reported an average of 7.69 side effects they had

experienced but only an average of .81 SCBs they had initiated with an average effectiveness rating of 3.05 on a five-point scale. The side effects with the greatest frequency were NV reported by 83% of patients. Patients initiated self-care most frequently for NV (50 SCBs) were reported. The SCBs most frequently initiated for alleviation of NV were taking a prescribed antiemetic and drinking a carbonated beverage. The findings supported the belief that SCBs can be learned. Analyses of covariance demonstrated a significant difference in average SCBs performance scores between patients who received SEMT information and those who did not [$F(1,44) = 7.60$, $p < .01$]. Before interventions, there was a significant positive relationship between severity of side effect and initiation of self-care ($r = .38$, $p = .007$). This relationship continued to be statistically significant for patients who did not receive SEMT information ($r = .41$, $p = .04$) (Dodd, 1983). The limitations of this study were the multiple diagnostic categories and chemotherapy protocols, and small sample size. The strength was data collectors were blind to the treatment conditions the patients had been randomly assigned to.

The second study on SCBs was focused on breast cancer patients ($N = 30$), who were initiating their first course of chemotherapy. These patients recorded in a log developed by

Dodd the side effects of treatment they were experiencing and the preventive self-care activities they undertook. The data were obtained by two interviews six to eight weeks apart. Potential moderator variables measured were the State Trait Anxiety Inventory, Multidimensional Health Locus of Control and the patients' perception of the purpose for chemotherapy. The four most frequently recalled potential side effects of chemotherapy were nausea, loss of hair, vomiting, and mouth sores. The average number of initiated SCBs the patients reported was .9. The mean state anxiety score and mean trait anxiety score for the first interview were 36.3 (SD = 10.1), and 34.8 (SD = 7.8), respectively. There was a significant negative relationship between state anxiety scores at the first interview and preventive self-care activity (r = -.41, p = .046) (Dodd, 1984c).

The strength of this study was to replicate and extend the findings of earlier research studies; to limit the sample to one type of malignancy; and to have the patients record their SCBs in a Self-Care Behavior Log (SCBL) during the 6-8 weeks study instead of relying on recall as in earlier studies. The findings revealed an overall average of 1.6 (SD = .94) SCBs. There was a significant positive correlation between the patients' ratings of severity of side effects and their delay in initiating SCBs (r = .5, p = .025). The breast cancer patients cited themselves most

frequently (60%), then the physician (25%), and lastly the nurse (7%) and the family (7%) as the source of self-care information. The average severity rating of the experienced side effects was 3.1 (SD = .5); and the average distress rating was 3.0 (SD = .6) both were rated on a five-point scale. The breast cancer patients' rating of the severity and distress of experienced side effects were significantly related (r =.65, p = .002). The decrease in state anxiety was significant [$t(29) = 2.20$, p =.04] between the two interviews. There was a significant positive relationship between the state anxiety scores at the second interview and the overall management of SCB ratio (r = .46, p =.29) (Dodd, 1988).

Dodd designed her third longitudinal descriptive study SCBs for the side effects of radiation therapy (Dodd, 1984b). Thirty patients, who were initiating their first course of radiation therapy, were taught how to log the side effects of the treatment they experienced and the self-care activities they undertook. The findings of this study corroborate those of an earlier one of patients in chemotherapy. Patients reported experiencing an average of 3.3 side effects and initiating few (mean = 1.6, SD = .80) self-care activities. The most frequently initiated SCBs in experiencing nausea were to take Compazine, sit down and rest, or drink 7-up. A nonrandomized sample with various

diagnosis and treatments before radiation therapy limited the generalizability of the findings.

In 1987, Dodd published her fourth study on SCBs in cancer patients. The purpose of this quasi-experimental study (N = 60) was to test the efficacy of side effect management technique (SEMT) information if presented proactively. Three self-administered instruments were used: (a) SCBs, measured by the actions recorded in the SCBL, (b) Anxiety, measured by the STAI, (c) Control, measured by the Cancer Health Locus of Control (CHLC) scale. Three hypotheses were posed. The first hypothesis stated that patients who received the proactive SEMT information would report more SCBs that prevent potential side effects and that alleviate experienced side effects of radiation therapy than would the control group patients. The second hypothesis stated that patients who received proactive SEMT information would initiate SCBs with less delay when a side effect occurred than would control patients. The third hypothesis stated that patients who received proactive SEMT information would initiate SCBs before an experienced side effect became more severe and distressing, unlike control patients, who would wait until a later stage. The findings only supported the first hypothesis in part. The most frequently initiated SCBs for nausea were to take an antiemetic agent, rest, or smoke marijuana. The limitations

were various types of malignancies in the sample and the confounding effect of keeping the SCB log on the delay pattern of initiating self-care activities.

The fifth study on SCBs in cancer patients had the same research design but for chemotherapy patients (N = 60) conducted by Dodd (in press). Results only showed that the first hypothesis was supported. Patients who received the proactive SEMT information reported significantly higher four SCB ratios than did the control group patients [$t(58)$ = 2.18-2.50, p = .015-034]. The variables of anxiety and control were not significantly associated with the SCB ratios. Patient, who received SEMT information, reported a significantly lower state anxiety score during the study period. The average state anxiety score was 43.3 at the preintervention interview and 34.87 at the postintervention interview, [$t(29) = -4.63$, p = .001] (Dodd, in press).

Theoretical Framework

The theoretical bases for this study was provided by pathophysiological theories which describe the phenomena of NV and Orem's Self-Care Deficit conceptual model.

Pathophysiological Theories

NV are a part of the body's natural homeostatic protective system which helps rid itself of noxious stimuli and substances. Utilizing a negative feedback mechanism, sensors at various locations in the body, when stimulated,

send afferent nerve impulses to a central area (Needleman, 1987). The vomiting center is located in the lateral reticular formation of the medulla. The Chemoreceptor Trigger Zone (CTZ) is located in the area postrema of the fourth ventricle and various visceral afferent and efferent connections (Hanson & McCallum, 1985).

The severity of post-chemotherapy emesis is related to the intensity of the emetogenic stimulus. The reflex is coordinated by the vomiting center of the medulla and activated by stimulation of the alimentary canal, especially in the duodenum, and by stimulation of nausea, odors, nauseous sights, seasickness, and emotional upset (Beyer & Dudas, 1984). The CTZ may be activated by chemical stimuli circulating in either the blood or cerebrospinal fluid.

One postulated mechanism of vomiting states that vomiting after chemotherapy is mediated through the vomiting center and frequently appears to involve the CTZ. A second postulated mechanism of chemotherapy-induced vomiting is thought to be direct stimulation from the pharynx and gastrointestinal tract by afferent impulses transmitted via the vagus and sympathetic nerves to the vomiting center. It has been postulated that neuroreceptors (dopamine, opiate, histamine, cholinergic) located in the CTZ and gastrointestinal tract have an important role in mediating these impulses. A third postulated mechanism for vomiting

involves afferent impulses from supramedullary loci that may produce emesis and anticipatory vomiting. Thus, there are three primary pathways believed to direct afferent impulses to the vomiting center, which will in turn emit efferent impulses to produce vomiting (Fortner, Finley, & Grove, 1985; Gralla, Tyson, Kris, & Clark, 1987; Needleman, 1987; Petton, 1984).

Patients did perceive negative side effects associated with chemotherapy (Todres, Wojtiuk, 1979). In particular, anxiety had been suggested to be an important factor in anticipatory NV (Rhodes et al., 1986). The conscious perception of discomfort (i.e. nausea) associated with vomiting from any causes was a cerebral function, as must also be the origin of "anticipatory emesis" or conditioned vomiting. It was already apparent that the psychological conditioned element of chemotherapy-induced vomiting could be treated as a separate phenomenon from the immediate pathophysiological response to chemotherapy (Borison & McCarthy, 1983). Rhodes and associates (1987) have found statistically significant relationships between post-chemotherapy symptom experience (for nausea and vomiting) and antineoplastic drug protocol (Rhodes, Watson, Johnson, Madsen, & Beck, 1987). Cyclophosphamide is a agent with high emetic incidence (60-90%); onset: 4-12 hours; duration: 4-10 hours; response proportional to dose; nausea

and anorexia common. 5-Fluorouracil is a agent with moderate emetic incidence (30-60%); onset: 3-6 hours; emesis can be dose-limiting; nausea and anorexia common. Methotrexate is a agent with low emetic incidence (10-30%); onset: 4-12 hours; duration: 3-12 hours; cumulative toxicity that is dose-related (Borison & McCarthy, 1983).

Orem's Self-Care Deficit conceptual model

Orem developed her self-care deficit theory of nursing as a general theory and several of the studies presented earlier have used Orem's model as a bases for their investigations in the cancer population. Orem defined self-care as deliberate action and learned behavior. Orem also mentioned that understanding self-care as deliberate action with internal and external orientations is important for nurses. The four types of externally oriented self-care actions include the following: (a) knowledge-seeking action sequences, (b) assistance-and resource-seeking action sequences, (c) expressive interpersonal actions, and (d) action sequences to control external factors. The two types of internally oriented self-care actions include the following: (a) resource-using action sequences to control internal factors and (b) action sequences to control oneself (thoughts, feelings, orientation) and thereby regulate internal factors or one's external orientations (Orem, 1985, p.110). From a nursing point of view, human beings are

viewed as needing continuous self-maintenance and self-regulation through a type of action named self-care. The term self-care means care that is performed by oneself for oneself when one has reached a state of maturity that is enabling for consistent, controlled, effective, and purposeful action (Orem, 1985, p.39). Orem stated that the function of nursing is to focus on the "maintenance of self-care activities individuals continuously need to sustain life and health, recover from disease and injury, and cope with their effects" (Orem, 1980, p.6). The goal of nursing is to help individuals to achieve good health. The nurse functions as a resource and facilitator in decision-making process of the client (Dickson & Lee-Villasenor, 1982). The findings of Dodd's study (1984c) demonstrated that the average number of SCBs initiated by breast cancer patients receiving chemotherapy were .9. The deficit of self-care agency is obvious and nurses need to formulate more interventions.

Purpose and Aims

The purpose of this study using a descriptive longitudinal research design (Brink & Wood, 1983) was to identify the patterns of SCBs for episodes of NV in two groups of outpatients with breast cancer who were undergoing either cycle 1 chemotherapy (Group A) or cycle two to six chemotherapy (Group B). Considering SCBs are learned

behaviors, patients in Group B might have more SCBs than Group A. In each group data were collected prior to and at a 12-hour interval after chemotherapy was given for a total of 72 hours (Time 1 through Time 7) (see Appendix A).

The aims of this study were:

Aim #1: to describe the post-chemotherapy patterns of NV in breast cancer patients;

Aim #2: to describe the frequency, duration and degree of distress from nausea experienced by breast cancer patients;

Aim #3: to describe the frequency, amount and degree of distress from vomiting experienced by breast cancer patients;

Aim #4: to describe the nature and frequency of SCBs initiated to alleviate the experienced NV from chemotherapy;

Aim #5: to determine the relationship of the duration of the experienced NV with the initiation of SCBs;

Aim #6: to determine the patient's perceived effectiveness of initiated SCBs for NV;

Aim #7: to identify the patient's sources of ideas for SCBs;

Aim #8: to determine the relationship of perceived severity and distress ratings of the experienced NV with the initiation of SCBs;

Aim #9: to determine the relationship of nausea and vomiting scores (both total and subscores) with initiation of SCBs;

Aim #10: to determine the relationship of potential moderator variables of anxiety and demographic variables with SCBs for NV.

Aim #11: to compare two groups of patients receiving cycle 1 Day 1 or Day 8 chemotherapy (Group A) with patients receiving at least their second cycle or more of chemotherapy (Group B) in the initiation of SCBs, patterns of NV, and anxiety level.

Operational Definitions

The three main variables in this study are NV; SCBs for NV; and patients' anxiety levels.

The instruments used in this study were: (a) adapted Rhodes Index of Nausea and Vomiting Scale Form 2 (RINV); (b) adapted Dodd's Self-Care Behavior Log (SCBL); (c) Spielberger's State and Trait Anxiety Inventory Scale (STAI); (d) Demographic Data Inventory (see Appendix B, C, D & E, respectively).

Nausea. The awareness of the urge to vomit, associated with one or more of the following factors: increased salivation, pallor, tachycardia, and cold sweats which occur more than 15 minutes after receiving chemotherapy, as measured by patient self-report using the RINV scale.

Vomiting. Sudden, forceful ejection of contents of stomach through the mouth (Wyngaarden & Smith, 1982). The operational definition of vomiting is that it results from receiving antineoplastic drugs, as measured by patient self-report using the RINV scale.

Patterns of Nausea and Vomiting. Patterns are the frequency, duration, amount, and distress of NV prior to (Time 1), at 12 hours (Time 2), 24 hours (Time 3), 36 hours (Time 4), 48 hours (Time 5), 60 hours (Time 6), and 72 hours (Time 7) after chemotherapy administration, as measured by the patient self-report RINV scale.

Self-Care Behaviors for Nausea and Vomiting. The SCBs are actions initiated by the patient (family or friends) to alleviate NV, as measured in the self-report record of the SCBL.

Anxiety. An emotional state causing increased autonomic nervous system anxiety measured by the STAI (A-State and/or A-Trait). The A-State scale measures disposition to respond to stressful situations with varying levels of A-State intensity and the degree of which presenting stimuli are perceived as a threat. The A-Trait scale elicits data on the subject's general level of arousal and is predictive of anxiety proneness.

CHAPTER THREE

Methodology

Research Design

This study used a descriptive longitudinal research design with a nonrandomized sample. The replication and extension of the studies of Rhodes and Dodd were by adding more data collection period from 48 hours to 72 hours, and focusing on NV.

Subject Selection

Criteria for participation in this study required that the subjects be: (a) 18 years or older, (b) mentally and physically competent, (c) able to understand Mandarin or Taiwanese, and read and write Chinese, (d) diagnosed as having breast cancer, (e) scheduled to begin or continue a course of chemotherapy, and (f) female.

Setting

Data collection occurred at a more than 1500-bed private general teaching hospital in northern Taiwan, Republic of China. Breast cancer patients usually were followed by their own surgeon after mastectomy. They received the prescription from the surgeon and brought the chemotherapeutic agents to the chemotherapy room, which was furnished with seven beds and six comfortable chairs. One trained oncology nurse prepared and administered the chemotherapy regimens to the patients.

Instruments

Adapted Dodd's Self-Care Behavior Log (SCBL). In this log, the patient records NV episodes instead of all side effects from chemotherapy. The patient indicates the time of onset and on two 5-point Likert scales, the severity (from "1" barely noticeable to "5" most severe) and distress experienced (from "1" minor annoyance to "5" extremely distressing). The patients also record what they do to alleviate NV and the time this activity takes place. The patients' perceptions of the effectiveness of each SCB is obtained on the third 5-point Likert scale from "1" not relieved at all to "5" completely relieved. Finally, the patient records the sources of information for each SCB. Four ratios were established by Dodd to examine the quantitative variable SCB:

1. Selected SCB ratio:

$$\frac{\text{Sum of "selected" SCBs}}{\text{Total number of experienced side effects}}$$

SCBs with an efficacy of "four" or "five" are excluded since it is not reasonable to expect further activity with a high degree of effectiveness to alleviate a side effect.

2. Total SCB ratio:

$$\frac{\text{Total number of SCBs}}{\text{Total number of experienced side effects}}$$

3. SCB Efficacy ratio:

$$\frac{\text{Total effectiveness of each SCB}}{\text{Total number of SCBs}}$$

4. SCB Overall Management ratio:

$$\frac{\text{Total "highest" effectiveness rating of SCBs for each side effect}}{\text{Total number of experienced side effects}}$$

Content validity was established by two groups of oncologists and four oncology clinical nurse specialists. The reliability of the SCBL was established by the test-retest method with a control group (r = .88, p <.001) (Dodd, 1982a, 1984b, 1988).

Adapted Rhodes Index of Nausea and Vomiting (RINV). The Rhodes INV Form 2 is a 8-item, 5-point Likert-type self-report pencil and paper tool that measures the patient's perceived frequency of nausea, duration of nausea, and distress from nausea; frequency of vomiting, amount of vomiting, and distress from vomiting; frequency of dry heaves, and distress from dry heaves. The scale ranges from 0 "During last 12 hours I have not felt or experienced nausea or vomiting" to 4 "During last 12 hours I felt severe distress from nausea or vomiting". Cronbach's Alpha was calculated for Form 2 with a reliability estimate to be .98. The internal reliability of the INV Form 1 was determined by using a split-half procedure and Cronbach's Alpha. Cronbach's Alpha was calculated for 12 administrations with

reliability estimates of .89 to .97 (N = 25 to 30). The split half procedure yielded reliability estimates of .83 to .99 (n = 25 to 32) with 11 of the 12 administrations yielding reliability estimates greater than .90. Concurrent validity was assessed by comparing the ratings of chemotherapy patients with ratings of family members. Correlations using the Spearman Formula were calculated for two separate administrations across 2 cycles of chemotherapy. The correlations for the first and for the second administration were r = .89 (N = 18) and r = .83 (N = 16), respectively. Construct validity was established between groups of well citizens (N = 72) and chemotherapy patients (N = 32) (p =.0003) and was determined by using the Mann-Whitney U test (Rhodes, Watson, & Johnson, 1983, 1984, 1986, 1987). This tool is reliable and valid in measuring post-chemotherapy NV in cancer patients. Because the concept of retching or dry heaves is confused easily with nausea in Chinese, two items related to dry heaves were deleted. The adapted Rhodes Index of Nausea and Vomiting (RINV) used in this study had only 6 items (see Appendix B).

The total score of NV was calculated by summing the patients' responses to each of the six items on the RINV; the potential range of scores was from 0 to 24; the actual range was 0 to 21. The nausea subscore was calculated by summing the patient's responses to the frequency, duration,

and distress of nausea items on the RINV; the potential range of scores was from 0 to 12; the actual range was 0 to 11. The vomiting subscore was calculated by summing the patients' responses to the frequency, amount, and distress of vomiting items on the RINV; the potential range of scores was from 0 to 12; the actual range was 0 to 11.

The nausea subscore in the RINV included the sum of 3 items: frequency of nausea, duration of nausea, and degree of distress from nausea. Each item ranged from "0" to "4," e.g., for frequency of nausea, "0" represents the statement "I did not feel nauseated or sick at my stomach during the last 12 hours"; "4" represents the statement "I felt nauseated or sick at my stomach 7 or more times during the last 12 hours".

The vomiting subscore in the RINV also included the sum of three items: frequency of vomiting, amount of vomiting, and degree of distress from vomiting. Each item was rated from "0" to "4," e.g., for amount of vomiting, "0" represents the statement "During the last 12 hours I did not throw up"; "4" represents the statement "During the last 12 hours I produced a very large (3 cups or more) amount each time I threw up".

State-Trait Anxiety Inventory (STAI). The STAI consists of two 20-item scales that measure two distinct anxiety concepts, state anxiety (A-State) and trait anxiety

(A-Trait). The STAI has proven to be useful in clinical situations. The A-Trait tool provides a means for screening subjects for anxiety-proneness and for evaluating the degree to which subjects are troubled by neurotic anxiety problems. The A-State tool measures the level of transitory anxiety and evaluates feelings of tension, nervousness, worry, and apprehension. The items are measured on a four-point Likert self-report scale ranging from 1 (not at all) to 4 (very much so). The range of possible scores on each subscore is 20 to 80. Reliability data range from .16 to .54; alpha coefficient range from .83 to .92, typically higher under stress; construct validity, point biserial ranges from .60 to .73. Correlations with other standard trait anxiety instruments have been established: IPAT Anxiety Scale (.75 to .77); Taylor Manifest Anxiety Scale (.79 to .83); and Affect Adjective Checklist (.51 to .52). Construct validity have been determined by subjecting participants to testing under stress and non-stress conditions (Spielberger, Gorsuch, & Lushene, 1970).

Demographic Data Inventory. The demographic data included age, ethnic background, religious preference, marital status, living arrangement, disease process and treatment, previous experience related to cancer, and Karnofsky's performance status.

The instruments were translated into Chinese. Content validity of the translation was established by two oncology clinical nurses from Taiwan who are fluent in Chinese and English and are graduates from Master degree at the University of California, San Francisco (UCSF).

Human Subjects Assurance

The research protocol was approved by the UCSF Committee on Human Research (see Appendix N). Questionnaires contained no identification of the individual, and confidentiality of the subjects responses was maintained throughout the study. Subject participation was strictly voluntary, with freedom to withdraw at any time. Patients were assured that they would remain anonymous, that no invasive procedure would occur as part of the study, that non-participation in the study would not affect their medical care, and that they would not incur any financial costs from their participation in the study. Signed consent forms were kept in a locked file cabinet at the investigator's residence (see Appendix F).

Procedure

Each recruited subject was approached in the morning to prevent from disturbing her sleep, since data were collected twice a day at 12-hour intervals (e.g., 10 am and 10 pm) for 72 hours by patient self-report questionnaires.

1. The investigator approached each potential participant to give her verbal and written information about the study.

2. If the patient consented, the following demographic information: diagnosis; age; place of residence; antineoplastic and antiemetic drugs ordered including dosage, route, date, and time; and other drugs administered dosage, route, date, and time; were completed by an interview and checking the patients' hospital records.

3. The patient was asked to complete the RINV (Time 1) and the STAI (Time 1) before or during the chemotherapy treatment.

4. The investigator, then, gave the patient a package of questionnaires, including the RINV sheets, State Anxiety Scale and the SCBL, and explained how and when to complete each of them.

5. While the chemotherapeutic agents were being given, the investigator marked the exact time on the RINV sheets and asked the patient to respond to the RINV the evening following chemotherapy treatment (Day 1) and again every 12 hours for 72 hours (Time 2 through Time 7) (see Appendix A).

6. In the morning of post-chemotherapy Day 4 (Time 7) the patient was again asked to respond to the State Anxiety Scale, and to complete the last RINV; all questionnaires

then were put in a stamped addressed envelop and mailed to the investigator.

Data Analyses

Data analysis was conducted by the Crunch software statistical package (1987). Descriptive statistics, Mann-Whitney U test, Wilcoxon Signed-Ranks test, and Spearman's rank correlations were used because the sample size in each group was small.

CHAPTER FOUR

Results

Description of Sample

From June 23 to August 29, 1987, there were 34 breast cancer patients who were approached: Nineteen patients did not meet criterion "c" of subject selection; 3 patients did meet the criteria but refused to participate in the study because they were too busy; 12 patients did agree to participate in the study. There were 6 patients in Group A and 6 patients in Group B.

Table 1 shows the demographic characteristics of breast cancer patients in the study. All patients were married and lived with their families. Using Mann-Whitney U test to compare Group A with Group B on selected demographic variables found that age (z = .48, p < .630) and Karnofsky's performance status (z = .93, p < .352) had no significant differences; but there were significant differences in educational attainment (z = 2.00, p < .045), time since cancer diagnosis (z = 2.48, p < .013), and time since surgery (z = 2.92, p <.004) between the two groups (Table 1). Group A patients had higher education, their diagnosis and mastectomy were more recent than those in Group B. In Group A, 83.3% (n = 5) of the breast cancer patients knew that the purpose of chemotherapy was to cure cancer and shrink the tumor. In Group B, 66.7% of the breast cancer

patients (n = 4) were not sure of the purpose of chemotherapy. Four patients in Group A (67%) and 3 in Group B (50%) had one or two family members or friends who had breast or colon cancer. Those family members and friends all had surgery, but some had combined chemotherapy and radiation; one also was treated with traditional Chinese medicine.

None of the patients in this study had received chemotherapy, radiotherapy or hormonal therapy before their current chemotherapy. They all received 5-Fluorouracil 500 mg IV infusion, Methotrexate 50 mg IV push, and Cyclophosphamide 50 mg/d orally (1-5 mg/kg/d). From the patients' perspective, one cycle (28 days) meant that, for the first 2 weeks, they came to the clinic at regular intervals (e.g., Day 1 and Day 8) to receive their chemotherapy infusion and their oral prescription (Cyclophosphamide) for 14 days. Then, they took a 2-week break and came back for the same regimen; this was repeated for another 5 cycles.

Data obtained in this study were from Group A, who received cycle 1 Day 1 or Day 8 chemotherapy, and Group B, who received cycle 2 or more chemotherapy (Table 1).

Patterns of Nausea and Vomiting (for entire sample)

Aim #1. The first aim was to describe the post-chemotherapy patterns of NV in breast cancer patients.

Figure 1 shows the patterns of NV in breast cancer patients receiving chemotherapy, regardless of their cycles.

Wilcoxon Signed-Ranks tests found that the mean nausea subscores were larger than the mean vomiting subscores, and there were significant differences between them through all data collection periods except Time 7 (z = 1.96-2.37, p = .018-.0498) (Table 2). The total and nausea subscore peaked at 12 hours, whereas vomiting peaked at 24 hours, then declined to baseline (Time 1). The breast cancer patients' post-chemotherapy nausea subscores had insignificant relationships with post-chemotherapy vomiting subscores at the same data collection periods using the Spearman's rank coefficient (r = - .47-.52, n = 12, p = .122-.712) (Table 3). Chemotherapy-induced NV are proposed to be different concepts.

Patterns of Nausea

Aim #2. The second aim was to describe the frequency, duration, and degree of distress from nausea experienced by breast cancer patients. Figure 2 shows the patterns of nausea reported by these breast cancer patients. The scores for frequency and duration of nausea were not 0 at pre-chemotherapy, peaked at 12 hours period post-chemotherapy, and gradually declined to pre-chemotherapy levels. The distress of nausea peaked at 24 hours.

Patterns of Vomiting

Aim #3. The third aim was to describe the frequency, amount, and degree of distress from vomiting experienced by breast cancer patients. Figure 3 shows the degree of distress from vomiting, the amount and frequency of vomiting.

The frequency of nausea, duration of nausea, and distress from nausea were higher than the frequency of vomiting, amount of vomiting, and distress from vomiting. Table 4 shows that there were significant differences between frequency of nausea and frequency of vomiting at 36-60 hours post-chemotherapy, duration of nausea and amount of vomiting at 12-36 hours and 72 hours post-chemotherapy, and distress of nausea and distress of vomiting at 24-48 hours post-chemotherapy. There were insignificant relationships between the frequency of nausea and the frequency of vomiting, the duration of nausea and the amount of vomiting, and the distress of nausea and the distress of vomiting at all remaining data collection periods.

Self-Care Behaviors for Nausea and Vomiting

Aim #4. The fourth aim was to describe the nature and frequency of SCBs initiated to alleviate the experienced NV from chemotherapy. In this study, 6 patients did not fill out the SCBL completely, 2 in Group A and 4 in Group B. The remaining breast cancer patients' total SCB ratio was 1.21

(SD = 1.35), the selected SCB ratio was .93 (SD = 1.48), the SCB efficacy ratio was 1.68 (SD = 2.22), and the SCB overall management ratio was 2.93 (SD = 3.28) (Table 5). The most frequent initiated SCBs to alleviate the experienced nausea were to drink hot water, tea, soup or milk; rest or sleep; or eat fruit. The SCBs to alleviate the experienced vomiting were to drink tea, rest, or briefly exercise. Within 3 days post-chemotherapy, the breast cancer patients did initiate one to four SCBs to eliminate their experienced NV induced by chemotherapy.

Aim #5. The fifth aim was to determine the relationship of the duration of the experienced NV with the initiation of SCBs. None of the patients recorded the exact time they initiated the SCBs for NV in their logs and data are not available for analyses of this study aim.

Effectiveness of SCBs for Nausea and Vomiting

Aim #6. The sixth aim was to determine the patient's perceived effectiveness of initiated SCBs for NV. The mean SCB efficacy ratio was 1.68 (SD = 2.22) on a 5-point scale. Breast cancer patients did initiate some SCBs to alleviate their post-chemotherapy NV, but they rated the effectiveness of these SCBs rather low.

Sources of Ideas for SCBs

Aim #7. The seventh aim was to identify the patient's sources of ideas for SCBs. Four breast cancer patients

(33.3%) cited themselves as the source of their SCB ideas. These SCBs included taking a nap or rest; drinking hot soup, water or tea; eating a little bit of sugar-cured fruit to alleviate the NV. Two patients (16.7%) cited their husbands as the source of the SCB information. Suggestions included giving a back massage or drinking milk. Another patient reported that her mother-in-law suggested to her to drink a glass of milk to alleviate discomfort. Not surprisingly, no patients cited nurses or physicians as resource persons in the alleviation of NV.

Relationship between Severity and Distress of NV and SCBs for NV

Aim #8. The eighth aim was to determine the relationship of perceived severity and distress ratings of the experienced NV with the initiation of SCBs. No data were available for the severity and distress of NV in SCBL. However, the degree of distress from NV also were rated in the RINV scale. Spearman's correlation between distress of NV and four SCB ratios found no significant relationships between perceived distress from NV and the four SCB ratios.

Relationship between SCBs for NV and RINV Scores

Aim #9. The ninth aim was to determine the relationship of NV scores (both total and subscores) with SCBs (4 ratios). No significant relationships between any of the four SCB ratios and the RINV total scores, nausea

subscores, and vomiting subscores at any of the seven data collection periods were found on the entire sample. Of the four SCB ratios, only the SCB efficacy ratio and SCB overall management ratio showed a significantly negative relationship (Spearman's correlations) with the RINV total score at 12 hours post-chemotherapy in Group A patients (r = - .98, n = 4, p = .023; r = - .96, n = 4, p = .040, respectively). It meant patients receiving initial chemotherapy, the higher scores of the RINV they had, the lower SCB ratios in management and efficacy.

Aim #10. The tenth aim was to determine the relationship of potential moderator variables as anxiety and demographic variables with SCBs for NV.

Relationship between Anxiety and SCBs for NV. There was one missing data point on the state anxiety score post-chemotherapy in Group B. Spearman's correlations between all four SCB ratios and State and Trait Anxiety scores in this study were not significantly correlated.

Relationship between Demographic Variables and SCB for NV. Spearman's correlations between the four SCB ratios and selected demographic variables (age, education, time since cancer diagnosis, time since surgery, and Karnofsky's performance status) were computed. No significant relationships between them were found. In Group A, the SCB efficacy ratio and SCB overall management ratio were

positively correlated with education (r = .97, n = 4, p = .035; r = .99, n = 4, p = .009, respectively). It meant patients receiving initial chemotherapy, the more education attainment they had, the more manageable and efficient SCBs.

Comparison between Group A and Group B

Aim #11. The eleventh aim was to compare the two groups of patients receiving Cycle 1 Day 1 or Day 8 chemotherapy (Group A) and those patients receiving their cycle 2 or more chemotherapy (Group B) in SCBs, patterns of NV, and anxiety levels.

Self-Care Behaviors. Table 5 shows all means of four SCB ratios in Group B were higher than Group A. However, Mann-Whitney U test found that there were no significant differences between Group A and Group B in the four SCB ratios: selected SCB ratio (z = .64, p < .522, $d.f.$ = 5), total SCB ratio (z = 1.22, p < .223, $d.f.$ = 5), SCB efficacy ratio (z = .47, p < .639, $d.f.$ = 4), and SCB overall management ratio (z = 1.41, p < .159, $d.f.$ = 4).

RINV Scores. Figure 4, 5, and 6 shows Group B was higher than Group A on RINV total scores, nausea subscores, and vomiting subscores at all data collection periods. Using Mann-Whitney U test, there were significant differences between Group A (n = 6) and Group B (n = 6) in total score at 24 hours and 60 hours post-chemotherapy (z = 2.21, p <.028; z = 1.97, p < .049, respectively) and nausea

subscore at 24 hours post-chemotherapy (z = 2.13, p < .033). No significant differences between Group A and Group B in vomiting subscores at all data collection periods were found (Table 6). There were significant differences between mean nausea subscores and mean vomiting subscores in Group B at 36 hours and 60 hours post-chemotherapy (z = 2.04, p =.041; z = 2.03, p = .042, respectively). There were no significant differences between the subscores in Group A (Table 2).

State Trait Anxiety Scores. In this study the breast cancer patients' mean state anxiety score pre-chemotherapy was 47.83 (SD = 9.65), the mean trait anxiety score was 44.08 (SD = 9.55). The patients' mean state anxiety score post-chemotherapy in Group A was higher than their pre-chemotherapy score, but this difference was statistically not significant. For Group B, the mean state anxiety score post-chemotherapy was lower than their pre-chemotherapy score, but this difference was statistically insignificant (Table 7).

No significant relationships between state anxiety scores pre-chemotherapy and state anxiety scores post-chemotherapy, and the state anxiety score and trait anxiety score pre-chemotherapy were found in Group A and Group B. Mann-Whitney U test also found no significant differences between Group A and Group B in State-Trait

Anxiety pre-chemotherapy (z = .24, p < .810; z = .16, p < .873, respectively), and State Anxiety post-chemotherapy (z = .27, p < .748).

CHAPTER FIVE

Discussion

The findings of this study partially corroborated the research studies of Dodd (1984c, 1988) and Rhodes et al (1985, 1987). It contributes to a better understanding of breast cancer patients' SCBs for chemotherapy induced NV.

SCBs for NV

The average number of SCBs for NV initiated by the breast cancer patients in this study was 1.21 (*SD* = 1.35). It was lower than the overall average of 1.6 (*SD* = .94) SCBs in Dodd's findings (1988). The SCB efficacy ratio (*M* = 1.68, *SD* = 2.22) was also lower than in Dodd's study (*M* = 3.0, *SD* = 1.4). No patients mentioned nurses or physicians as their resource persons in the study. Therefore, more nursing interventions and patient education are needed to alleviate chemotherapy side effects, especially nausea and vomiting, in breast cancer patients.

The pattern of SCBs was very similar between this study and Dodd's studies. Patients used home remedies, however Dodd's samples used more antiemetics. Also mentioned Group B were more active in their self-care, apparently the repeating cycles of chemotherapy increased NV and provided the stimulus for more SCBs.

Patterns of NV

Patterns of NV in this study supported the findings in the studies of Rhodes, Watson and Johnson (1985, 1987). The patterns of nausea and the patterns of vomiting are two different phenomena. The most severe NV were at 12 hours and 24 hours post-chemotherapy. This reflects higher drug doses in the blood and these gradually decreased. Patients receiving more than one cycle of chemotherapy experienced significantly more frequent, duration, amount, and distress from nausea and vomiting which may suggest that these side effects are cumulative. Also the destress from nausea took time to developed i.e., it peaked at 24 hours. Similarly, vomiting peaked later than nausea.

Anxiety Levels

In this study the breast cancer patients' mean state anxiety score and mean trait anxiety score pre-chemotherapy were higher than Dodd's finding (1988) [36.3, (SD = 10.1) for state anxiety and 34.8 (SD = 7.8) for trait anxiety at the first interview] and Rhodes' finding (1986) [40 (SD = 8.5) for state anxiety before chemotherapy]. The reason might be lack of information and support system in Taiwan to cope with disease process and side effects of treatment. However, it was lower than the findings of Scott (1983). The STAI has been used in a sample of breast biopsy patients (N = 85). Scott reported an average patient score of 48.7 (SD = 10; state) at the time of biopsy. Breast cancer

patients' anxiety level may be related to diagnosis, disease process, and reactions of treatment. Further investigation in this area needs to occur.

Environmental factors also influenced these breast cancer patients' perceived severity of NV. For example, it was easy to observe that the patients were influenced by each other's reactions when they felt nauseated or vomited in the same room. Since the chemotherapy room is large, with no separation between beds and chairs, patients can observe and communicate with each other. Once, when one patient had severe NV after antineoplastic drugs had been administered, some of the patients in the room were affected. Few physicians prescribed antiemetics for the breast cancer patients. It might be their nausea and vomiting not so severe or patients did not complain to their physician. One breast cancer patient felt nauseated and received her antiemetics. However, she told me that antiemetics made her feel sicker, so she threw them away. Another issue which might influence NV is whether antiemetics are appropriately prescribed and taken by the patients. This question needs further investigation.

Patients in group A, who were receiving their chemotherapy for the first time, behaved differently in the chemotherapy room than those patients who had been there before. They usually looked around and observed the entire

environment. They often asked nurses or other patients questions, possibly to feel better in control of the new situation. In contrast, some of the patients who had come to the chemotherapy room before, tended not to say anything; usually, but just put the drugs on the desk and went to the bathroom. Afterwards, the repeating patients lied down on a bed or sat in a comfortable chair, waiting for the nurse to set up the intravenous infusion. Some patients mentioned that, as soon as they stepped in the building, they felt sick to their stomach. Some of the breast cancer patients were afraid of the smell in the chemotherapy room. For example, one patient covered her nose and mouth with a handkerchief. One patient always wore a mask when she came to the chemotherapy room. Different patients had different coping strategies and SCBs. There were no significant relationships between SCBs for NV and patient's anxiety level in this study. Nurses still need to learn more about individualized SCBs in order to establish and test more effective nursing interventions.

Self-report Instruments

To be able to use a self-report questionnaire, the participant needs at least 6 years of schooling in Chinese. However, 40 years ago Taiwan was under Japanese control. Most of the people did not have a chance to go to school, especially females. Some of them learned Japanese only.

The mean age of breast cancer patients whom the investigator approached was 44.9 years (N = 34); they ranged in age from 28 to 65 years old. They were younger than those breast cancer patients in the Dodd's study (mean = 54.6, SD = 10.43) (Dodd, 1984c, 1988). When the investigator asked them about their educational background, some of them mentioned that it was not easy to survive at that time, let alone to learn Chinese. This is only one factor of a complex social and historical background which influenced this population. Further, the fact that these self-report instruments are geared towards white middle-class Americans, their administration to Chinese patients needs to be taken into account in the interpretation of the study's findings.

Multidisciplinary Approach

A cancer center has not yet been established in Taiwan. Most of the breast cancer patients are cared for by the physician who first sees them. After mastectomy, the breast cancer patient is still followed by the physician in the surgical clinics, where she also received her chemotherapy treatment. There are seldom referrals between surgical and medical oncologists. Some of the patients complained that their surgeons were not concerned about the side effects of treatment (CMF). They complained that they spent a whole morning waiting for the doctor, but that the doctor only gave them less than a minute. Some of the patients were

afraid that the doctors might be angry with them and not care for them appropriately if they had too many requests or questions. They would rather not let their doctors know their distress from treatment even though they were dissatisfied with his care. Some of the patients did not know the treatment plan and the side effects of the treatment. They only knew they would come back next week to get another treatment. The nurses working in the clinics also whispered that they felt powerless about patients' complaints. They also thought that the doctors were not concerned about the patients' physical discomfort and the patients' side effects induced by cancer chemotherapy.

Since cancer care needs a multi-disciplinary approach, it is crucial to develop a collaborative attitude between nurses and medical and surgical oncologists. Using a multidisciplinary approach in cancer treatment and side effects management also needs to be stressed. Expanding the role and function of oncology nurses in patient education and interventions to alleviate side effects from chemotherapy needs to occur.

Limitations

This study is limited by the self-report instruments, with which the patients were not accustomed. There was no possibility to verify the accuracy of these measurements, either by observation or by interview with the patient's

family in this study. Also, the sample size was too small in each group to generalize findings, even though some of results had statistical significance, these may have occurred due to Type I error. The reader is cautioned to interpret these findings with care given the small non-probability sample.

Recommendations for Future Research

Because of the convenience sampling, the sample size should be larger and more homogeneous in each group i.e., receiving the same cycle or protocol of chemotherapy. In terms of the patient's commitment to the study (attrition), the first interview is crucial. The investigator should establish good rapport with the patient and carefully explain the instruments to make sure that the patient understands them. This is especially important for those whose educational background is limited. Furthermore, when using a survey to obtain data to prevent problems that may threaten internal validity, such as interviewer effects and response sets, the interviewer needs to show interest without revealing what may be considered as the "right" response. The use and effectiveness of antiemetics for NV also needs to be stressed and documented.

References

American Cancer Society (ACS) (1987, 1988). Cancer facts and figures. New York: ACS.

Beyers, M., & Dudas, S. (1984). The clinical practice of medical-surgical nursing. (2nd ed.). Boston, MA: Little, Brown and Company. p.286, 971.

Bonadonna, G., & Valagussa, P. (1981). Dose-response effect of adjuvant chemotherapy in breast cancer. The New England Journal of Medicine, 304, 10-15.

Bonadonna, G., & Valagussa, P. (1985). Adjuvant systemic therapy for resectable breast cancer. Journal of Clinical Oncology, 3(2), 259-275.

Borison, H., & McCarthy, L. (1983). Neuropharmacology of chemotherapy induced emesis. Drugs, 25 (Suppl. 1), 8-17.

Brink, P. J., & Wood, M. J. (1983). Basic steps in planning nursing research -- from question to proposal. (2nd ed.). Monterey, CA: Wodsworth Health Sciences Division.

Brown, J. (1987). Chemotherapy. In S. L. Groenwald (Ed.). Cancer Nursing: Principles and practice. Boston, MA: Jones & Bartlett. pp. 348-384.

Bryant, M. J., Gorton, S. J. (1982). Reporting of common bothersome toxicities of cancer chemotherapy effecting

quality of life. American Society of Clinical Oncology - Proceedings., 1, 68.

Carey, M. P., Burish, T. G., & Brenner, D. E. (1983). Delta-9-Tetra-hydracannabinol in cancer chemotherapy: Research problems and issues. Annals of Internal Medicine, 99(1), 106-114.

Cotanch, P. H. (1984). Measuring nausea and vomiting in clinical nursing research. Oncology Nursing Forum, 11(3), 92-94.

Cotanch, P., Hockenberry, M., & Herman, S. (1985). Self-hypnosis as antiemetic therapy in children receiving chemotherapy. Oncology Nursing Forum, 12(4), 41-46.

Crunch statistical package. (1987). [Computer program manual]. Oakland CA: Crunch Software Co.

Department of Health, The Executive Yuan, R.O.C. (1983). Cancer registry annual report in Taiwan area, 1981. pp.18-19.

Dickson, G. L., & Lee-Villasenor, H. (1982). Nursing theory and practice: a self-care approach. Advances in Nursing Science, 5(1), 29-40.

Dobkin, P., Zeichner, A., & Dickson-Parnell, B. (1985). Concomitants of anticipatory nausea and emesis in cancer patients in chemotherapy. Psychological Report, 56, 671-676.

Dodd, M. J. (1982a). Assessing patient self-care for side effects of cancer chemotherapy -- Part I. Cancer Nursing, 5, 447-451.

Dodd, M. J. (1982b). Cancer patients' knowledge of chemotherapy: Assessment and informational interventions. Oncology Nursing Forum, 9(3), 39-44.

Dodd, M. J. (1983). Self-care for side effects in cancer chemotherapy: An assessment of nursing interventions -- Part II. Cancer Nursing, 6, 63-67.

Dodd, M. J. (1984a). Measuring informational intervention for chemotherapy and self-care behavior. Research in Nursing and Health, 7, 43-50.

Dodd, M. J. (1984b). Patterns of self-care in cancer patients receiving radiation therapy. Oncology Nursing Forum, 11(3), 23-27.

Dodd, M. J. (1984c). Self-care for patients with breast cancer to prevent side effects of chemotherapy: A concern for public health nursing. Public Health Nursing, 1(4), 202-209.

Dodd, M. J. (1987). Efficacy of proactive information on self-care in radiation therapy patients. Heart & Lung, 16(5), 538-544.

Dodd, M. J. (1988). Patterns of self-care in patients with breast cancer. Western Journal of Nursing Research, 10(1), 7-24.

Dodd, M. J. (in press). Efficacy of proactive information on self-care in chemotherapy patients. Journal of Patient Education and Counseling.

Duigon, A. (1986). Anticipatory nausea and vomiting associated with cancer chemotherapy. Oncology Nursing Forum, 13(1), 35-40.

Frank, J. M. (1985). The effects of music therapy and guided visual imagery on chemotherapy induced nausea and vomiting. Oncology Nursing Forum, 12(5), 47-52.

Fernsler, J. (1986). A comparison of patient and nurse perceptions of patients' self-care deficits associated with cancer chemotherapy. Cancer Nursing, 9(2), 50-57.

Fortner, C. L., Finley, R. S., and Grove, W. R. (1985). Combination antiemetic therapy in the control of chemotherapy-induced emesis. Drug Intelligence and Clinical Pharmacy, 19(1), 21-24.

Gralla, R. J., Tyson, L. B., Kris, M. G., & Clark, R. A. (1987). The management of chemotherapy-induced nausea and vomiting. Medical Clinics of North American, 71(2), 289-301.

Grant, M. M. (1982). Environmental influences of the occurrence of chemotherapy-associated nausea and vomiting. Oncology Nursing Forum, 9(1),50-51.

Hanson, J. S., & McCallum, R. W. (1985). The diagnosis and management of nausea and vomiting: A review. American Journal of Gastroenterology, 80(3), 210-218.

Henderson, I. C., & Canellos, G. P. (1980). Cancer of the breast: The past decade. The New England Journal of Medicine, 302, 17-30, 78-90.

Kennedy, M., Packard, R., Grant, M. M., & Padilla, G. V. (1981). Chemotherapy related nausea and vomiting: A survey to identify problems and interventions. Oncology Nursing Forum, 8(1), 19-22.

Keys, H. M., Bakemeier, R. F., & Savlow, E. D. (1983). Breast cancer. In P. Rubin, R. F. Bakemeier, & S. K. Krackov (Eds.). Clinical oncology a multidisciplinary approach. (6th ed.). New York: American Cancer Society.

Laszlo, J. (1983). Nausea and vomiting as major complications of cancer chemotherapy. Drugs, 25 (Suppl. 1), 1-7.

Lindsey, A. M. (1985). Building the knowledge base for practice. Part I: Nausea and vomiting. Oncology Nursing Forum, 12(1), 49-56.

McAnena, O. J., & Daly, J. M. (1986). Impact of antitumor therapy on nutrition. Surgical Clinics of North America, 66(6), 1213-1228.

Meyerowitz, B. E., Sparks, F. C., & Spears, I. (1979). Adjuvant chemotherapy for breast carcinoma: Psychological implication. Cancer, 43, 1613-1618.

Meyerowitz, B. E., Watkins, I. K., & Sparks, F. C. (1983). Psychosocial implications of adjuvant chemotherapy: A two-year follow-up. Cancer, 52, 1541-1545.

Morrow, G. R. (1984). The assessment of nausea and vomiting: Past problems, current issues, and suggestions for future research. Cancer, 53(Suppl.), 2267-2280.

Needleman, R. (1987). Chemotherapy: An overview of nausea and vomiting in the cancer patient: Etiology and management of serious complications of chemotherapy. AAOHN Journal, 35(4), 179-182.

Oberst, M. T. L. (1978). Priorities in cancer nursing research. Cancer Nursing, 1(4), 281- 290.

Olafsdottir, M., Sjöden, P. O., & Westling, B. (1986). Prevalence and prediction of chemotherapy-related anxiety, nausea and vomiting in cancer patients. Behavior Research Therapy, 24(1), 59-66.

Orem, D. E. (1980). Nursing concepts of practice. (2nd ed.). New York: McGraw-Hill.

Orem, D. E. (1985). Nursing concepts of practice. (3rd ed.). New York: McGraw-Hill.

Palmer, P. (1987). Pre-chemotherapy patient education: Its effect on the pattern of nausea and vomiting. Master theses. University of California, San Francisco.

Penta, J. S., Poster, D. S., Bruno, S., Abraham, D., Pinna, K., and Macdonald, J. S. (1981). Cancer chemotherapy-induced nausea and vomiting: A review. in Poster, D. S., Penta, J. S., and Bruno, A. (1981). Treatment of Cancer Chemotherapy-Induced Nausea and Vomiting. New York: Masson Publishing USA Inc.

Petton, S. (1984). Easing the complications of chemotherapy a matter of little victories. Nursing 84, 14(2), 58-64.

Rhodes, V. A., Watson, P. M., & Johnson, M. H. (1983). A self-report tool for assessing nausea and vomiting. Oncology Nursing Forum, 10(1), 11.

Rhodes, V. A., Watson, P. H., & Johnson, M. H. (1984). Development of reliable and valid measures of nausea and vomiting. Cancer Nursing, 2, 33-41.

Rhodes, V. A., Watson, P. H., & Johnson, M. H. (1985). Patterns of nausea and vomiting in chemotherapy patients: A preliminary study. Oncology Nursing Forum, 12(3), 42-48.

Rhodes, V. A., Watson, P. M., & Johnson, M. H. (1986). Association of chemotherapy related nausea and vomiting

with pretreatment and post-treatment anxiety. Oncology Nursing Forum, 13(1), 41-47.

Rhodes, V. A., Watson, P. M., Johnson, M. H., Madsen R. W., & Beck, N. C. (1987). Patterns of nausea, vomiting, and distress in patients receiving antineoplastic drug protocols. Oncollgy Nursing Forum, 14(4), 35-44.

Scott, D. W. (1983). Anxiety, critical thinking and information processing during and after breast biopsy. Nursing Research, 32, 24-28.

Spielberger, C. D., Gorsuch, R. L., & Luchene, R. E. (1970). STAI, manual for the state-trait anxiety inventory. Palo Alto, CA: Consulting Psychologists Press.

Tancini, G., Bajetta, E., Marchini, P., Bonadonna, G., & Veronesi, V. (1979). Preliminary 3-year results of 12 versus 6 cycles of surgical adjuvant CMF in prememopausal breast cancer. Cancer Clinical Trails, 2, 285-292.

Todres, R., & Wojtiuk, R. (1979). The cancer patient's view of chemotherapy. Cancer Nursing, 2(4), 283-286.

Welch-McCaffrey, D. (1985). Cancer, anxiety, and quality of life. Cancer Nursing, 8(3), 151-158.

Wilcox, P. M., Fetting, J. H., Nettesheim, K. M., & Abeloff, M. D. (1982). Anticipatory vomiting in women

receiving Cyclophosphamide, Methotrexate, and 5-FU (CMF) adjuvant chemotherapy for breast carcinoma. Cancer Treatment Reports, 66(8), 1601-1604.

Wyngaarden, J. B. & Smith, L. H. (Eds.). (1982). Cecil Textbook of Medicine. (16th ed.). Philadelphia: W. B.

Yasko, J. M. (1985). Holistic management of nausea and vomiting caused by chemotherapy. Topics in Clinical Nursing, 7(1), 26-38.

Yates, J. W., Chalmer, B., & McKegney, F. P. (1980). Evaluation of patients with advanced cancer using the Karnofsky performance status. Cancer, 45, 2220-2224.

Zook, D. J., & Yasko, J. M. (1983). Psychologic factors: Their effects on nausea and vomiting experienced by clients receiving chemotherapy. Oncology Nursing Forum, 10(3), 76-81.

Table 1

Demographic Characteristics of Breast Cancer Patients Receiving Chemotherapy

	Group A (n = 6)			Group B (n = 6)		
Characteristics	range	mean	S.D.	range	mean	S.D.
Age (year)	28-50	38.3	9.05	29-53	40.0	9.45
Education (year)*	6-16	9.5	4.46	4-6	5.7	0.82
Time since Cancer Diagnosis (months) *	1-2	1.2	0.41	1-9	4.5	2.74
Time since Surgery (months) *	1-2	1.2	0.41	2-6	3.7	1.37
Karnofsky's Performance Status	89-100	94.5	6.03	89-100	98.2	4.49

Note. S.D. = Standard Deviation. * $p < .05$, significant difference between Group A and Group B using the Mann-Whitney U test.

Table 1 continued

	Group A (n = 6)		Group B (n = 6)	
Characteristics	(n)	%	(n)	%
Ethic				
Taiwanese	5	83.3	5	83.3
Hakka	1	16.7	0	0.0
Mandarin	0	0.0	1	16.7
Religion				
Taoist	5	83.3	5	83.3
Buddist	1	16.7	1	16.7
Occupation				
housewife	2	33.3	3	50.0
part-time work	1	16.7	2	33.3
full-time job	3	50.0	1	16.7
Cancer Diagnosis				
ductal carcinoma	3	60.0	3	50.0
medullary carcinoma	1	20.0	3	50.0
other	1	20.0 @		
Lymph Node				
positive	3	60.0	5	83.3
negative	2	20.0 @	1	16.7

Table 1 continued

	Group A (n = 6)		Group B (n = 6)	
Characteristics	(n)	%	(n)	%
Metastasis				
local	4	80.0	2	33.3
metastasis	1	20.0 @	4	66.7
C/T purpose of curing cancer?				
yes	5	83.3	2	33.3
not sure	1	16.7	4	66.7
C/T to shrink the tumor?				
yes	5	83.3	2	33.3
not sure	1	16.7	4	66.7
Cycle				
cycle 1 day 1	5	73.3		
cycle 1 day 8	1	16.7		
cycle 2 day 1			1	16.7
cycle 2 day 8			1	16.7
cycle 3 day 8			1	16.7
cycle 4 day 1			2	33.3
cycle 5 day 8			1	16.7

Note. @ = missing data.

Table 2

Comparison of RINV Mean Nausea Subscores and Mean Vomiting Subscores from Chemotherapy in Breast Cancer Patients **

	Group					
	A + B (N=12)		A (n=6)		B (n=6)	
Time RINV measured	z	p	z	p	z	p
Time 1	2.03	.042*	1.00	.317	1.83	.070
Time 2	1.96	.0498*	1.83	.068	1.08	.279
Time 3	2.25	.024*	1.34	.180	1.80	.072
Time 4	2.37	.018*	1.34	.180	2.04	.041*
Time 5	2.21	.027*	1.60	.109	1.60	.109
Time 6	2.21	.027*	1.00	.317	2.03	.042*
Time 7	1.80	.072	1.34	.180	1.13	.257

Note. * p < .05. ** = Wilcoxon Signed-Ranks Test.

Time 1 = pre-C/T; Time 2 = post-C/T 12 hours;

Time 3 = post-C/T 24 hours; Time 4 = post-C/T 36 hours;

Time 5 = post-C/T 48 hours; Time 6 = post-C/T 60 hours;

Time 7 = post-C/T 72 hours.

Table 3

Spearman's Correlations between RINV Nausea Subscores and Vomiting Subscores from Chemotherapy in Breast Cancer Patients

	Group					
	A + B		A		B	
Time RINV measured	N = 12 r	p	n = 6 r	p	n = 6 r	p
Time 1	.28	.427	@		.33	.524
Time 2	- .47	.166	@		- .71	.118
Time 3	.13	.712	@		.21	.688
Time 4	.36	.302	@		.56	.248
Time 5	.43	.216	.11	.836	.68	.135
Time 6	.52	.122	@		.73	.103
Time 7	.40	.253	@		.59	.214

Note. @ = S.D. = 0, it is not possible to compute a correlation. Time 1 = pre-C/T; Time 2 = post-C/T 12 hours; Time 3 = post-C/T 24 hours; Time 4 = post-C/T 36 hours; Time 5 = post-C/T 48 hours; Time 6 = post-C/T 60 hours; Time 7 = post-C/T 72 hours.

Table 4

Comparison of Frequency, Duration, Amount, and Distress between Nausea and Vomiting from Chemotherapy in Breast Cancer Patients (N = 12) **

Time RINV measured	@FON vs FOV	DuON vs AOV	DON vs DOV
Time 1	z=1.86 p=.063	z= 1.84 p=.066	z=1.41 p=.157
Time 2	z=1.62 p=.105	z= 2.15 p=.032*	z=1.73 p=.085
Time 3	z=1.84 p=.066	z= 1.98 p=.047*	z=2.23 p=.026*
Time 4	z=2.12 p=.034*	z= 2.23 p=.026*	z=2.04 p=.041*
Time 5	z=2.23 p=.026*	z= 1.91 p=.056	z=2.04 p=.041*
Time 6	z=2.04 p=.041*	z= 1.89 p=.059	z=1.63 p=.103
Time 7	z=1.63 p=.103	z= 2.06 p=.039*	z= .58 p=.564

Note. * p < .05. ** = Wilcoxon Signed-Ranks Test. @ FON vs FOV = frequency of nausea v.s. frequency of vomiting. DuON vs AOV = duration of nausea v.s. amount of vomiting. DON vs DOV = distress of nausea v.s. distress of vomiting. Time 1 = pre-C/T; Time 2 = post-C/T 12 hours; Time 3 = post-C/T 24 hours; Time 4 = post-C/T 36 hours; Time 5 = post-C/T 48 hours; Time 6 = post-C/T 60 hours; Time 7 = post-C/T 72 hours.

Table 5

Four Self-Care Behavior Ratios for Nausea and Vomiting from Chemotherapy in Breast Cancer Patients

SCB ratios	Group	n	mean	SD	Range
Selected SCB ratio	A+B	7	0.93	1.48	0-4
	A	5	0.50	0.71	0-1.5
	B	2	2.00	2.83	0-4
Total SCB ratio	A+B	7	1.21	1.35	0-4
	A	5	.70	.67	0-1.5
	B	2	2.50	2.12	1-4
SCB Efficacy ratio	A+B	6	1.68	2.22	0-5
	A	4	1.40	2.42	0-5
	B	2	2.25	2.48	0.5-4
SCB Overall Management ratio	A+B	6	2.93	3.28	0-8
	A	4	1.40	2.42	0-5
	B	2	6.00	2.83	4-8

Note. SD = Standard Deviation.

Table 6

Significant Differences Between Group A (n = 6) and Group B (n = 6) of RINV Total Scores, Nausea Subscores, and Vomiting Subscores in Breast Cancer Patients **

Time RINV Measured	Total Score d.f.= 10	Nausea Subscore d.f.= 10	Vomiting Subscore d.f.= 10
Time 1	z=1.79 p<.074	z=1.79 p<.074	z=1.00 p<.317
Time 2	z=1.95 p<.051	z= .97 p<.330	z=1.89 p<.059
Time 3	z=2.21 p<.028*	z=2.13 p<.033*	z=1.89 p<.059
Time 4	z=1.16 p<.245	z=1.16 p<.244	z=1.48 p<.140
Time 5	z=0.33 p<.739	z=0.33 p<.739	z=1.15 p<.252
Time 6	z=1.97 p<.049*	z=1.88 p<.060	z=1.90 p<.058
Time 7	z=0.77 p<.441	z=0.68 p<.494	z=1.48 p<.140

Note. * p < .05. ** = Mann-Whitney U Test

Time 1 = pre-C/T; Time 2 = post-C/T 12 hours;

Time 3 = post-C/T 24 hours; Time 4 = post-C/T 36 hours;

Time 5 = post-C/T 48 hours; Time 6 = post-C/T 60 hours;

Time 7 = post-C/T 72 hours.

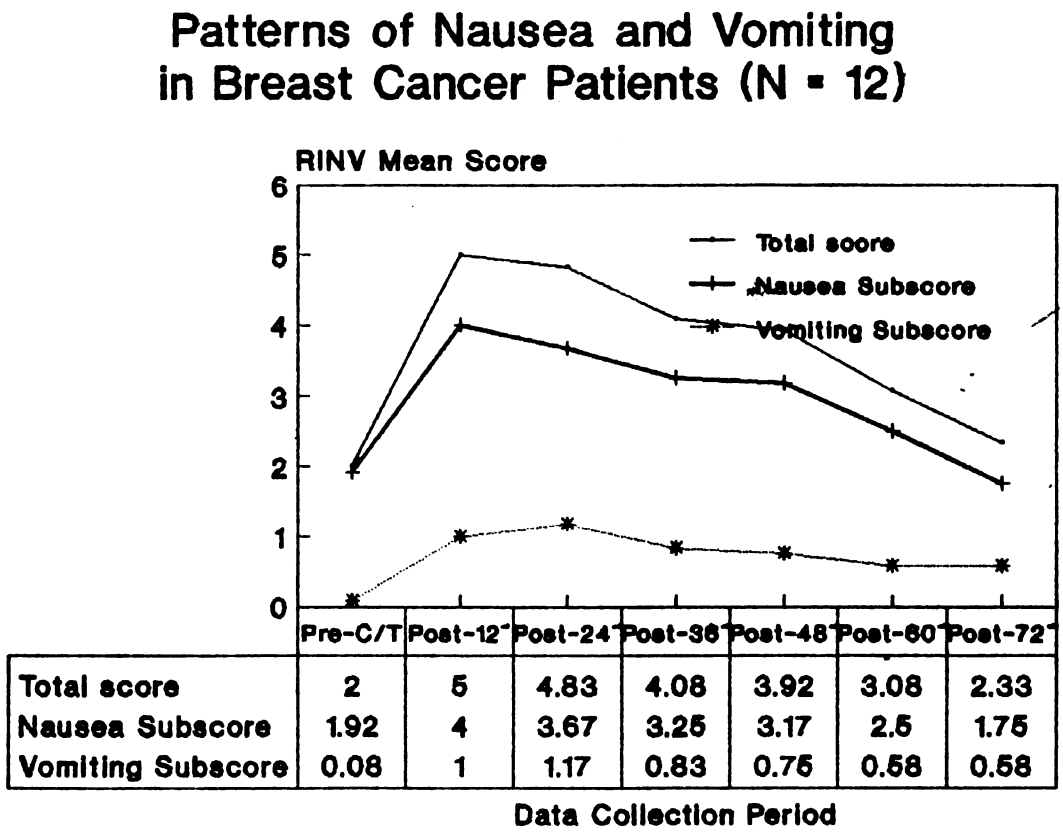
Table 7

Descriptive-Correlative Statistics of STAI Scores in Breast Cancer Patients

Group	STAI	Time	n	mean	S.D.	d.f.	r @	p
A+B	A-State	Time 1	12	47.83	9.65			
	A-State	Time 7	11	47.91	10.04	11	.64	.064
	A-Trait	Time 1	12	44.08	9.55	12	.48	.156
A	A-State	Time 1	6	46.83	11.50			
	A-State	Time 7	6	48.67	11.53	6	.74	.091
	A-Trait	Time 1	6	43.33	12.79	6	.56	.251
B	A-State	Time 1	6	48.83	8.38			
	A-State	Time 7	5	47.00	9.14	5	.42	.477
	A-Trait	Time 1	6	44.83	5.98	6	.31	.554

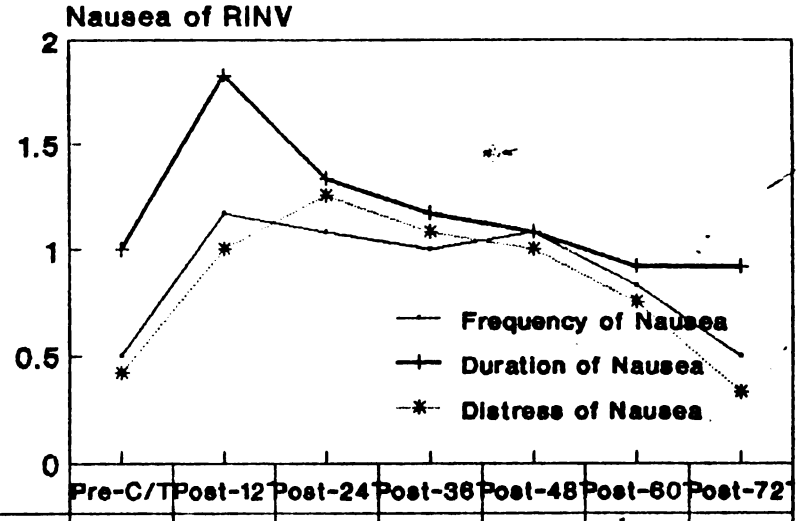
Note. @ = Spearman's correlations. Time 1 = pre-C/T; Time 7 = post-C/T 72 hours.

Figure 1. Patterns of Nausea and Vomiting in Breast Cancer Patients Receiving Chemotherapy.



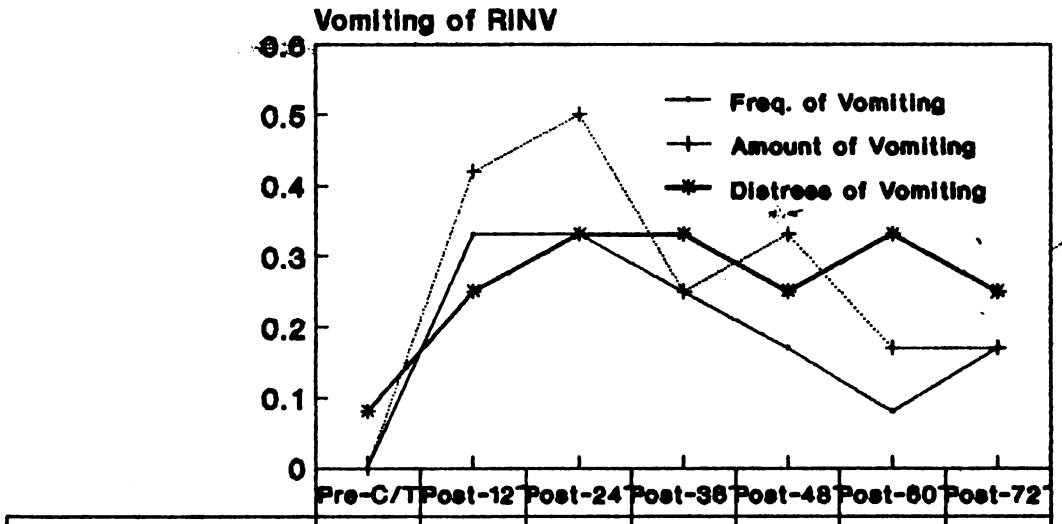
	Pre-C/T	Post-12	Post-24	Post-36	Post-48	Post-60	Post-72
Total score	2	5	4.83	4.08	3.92	3.08	2.33
Nausea Subscore	1.92	4	3.67	3.25	3.17	2.5	1.75
Vomiting Subscore	0.08	1	1.17	0.83	0.75	0.58	0.58

Figure 2. Patterns of Nausea in Breast Cancer Patients Receiving Chemotherapy.



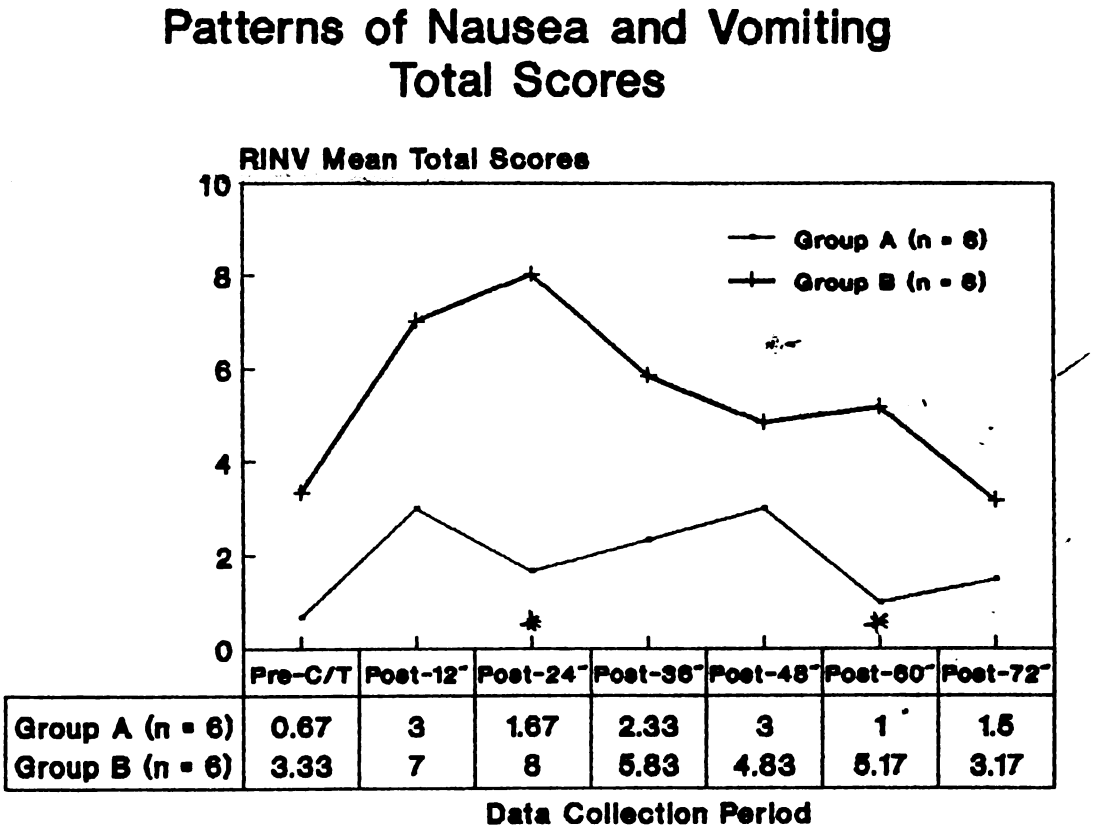
	Pre-C/T	Post-12	Post-24	Post-36	Post-48	Post-60	Post-72
Frequency of Nausea	0.5	1.17	1.08	1	1.08	0.83	0.5
Duration of Nausea	1	1.83	1.33	1.17	1.08	0.92	0.92
Distress of Nausea	0.42	1	1.25	1.08	1	0.75	0.33

Figure 3. Patterns of Vomiting in Breast Cancer Patients Receiving Chemotherapy.



	Pre-C/T	Post-12	Post-24	Post-36	Post-48	Post-60	Post-72
Freq. of Vomiting	0	0.33	0.33	0.25	0.17	0.08	0.17
Amount of Vomiting	0	0.42	0.5	0.25	0.33	0.17	0.17
Distress of Vomiting	0.08	0.25	0.33	0.33	0.25	0.33	0.25

Figure 4. Patterns of Nausea and Vomiting in Group A and Group B -- Total Scores.



	Pre-C/T	Post-12"	Post-24"	Post-36"	Post-48"	Post-60"	Post-72"
Group A (n = 6)	0.67	3	1.67	2.33	3	1	1.5
Group B (n = 6)	3.33	7	8	5.83	4.83	5.17	3.17

Figure 5. Patterns of Nausea and Vomiting in Group A and Group B -- Nausea Subscores.

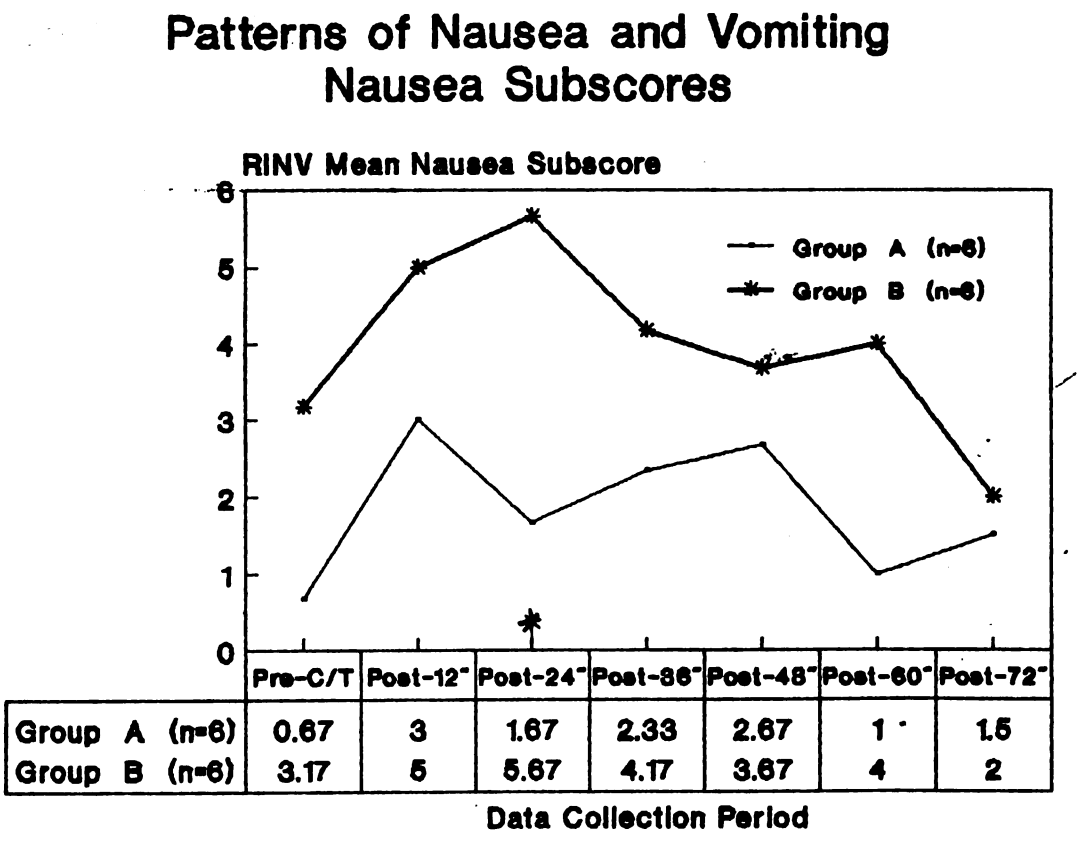
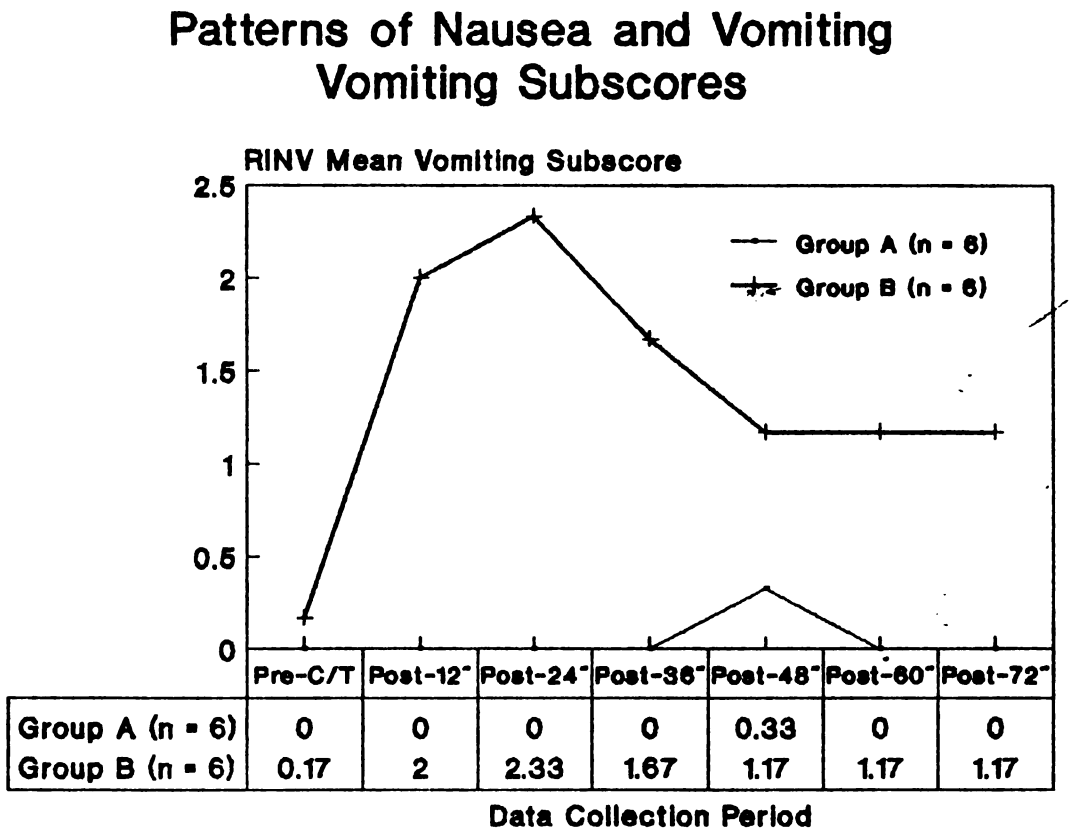


Figure 6. Patterns of Nausea and Vomiting in Group A and Group B -- Vomiting Subscores.



Appendix A

Time Table for Study

	Data Collection Period						
Instruments	Time1	Time2	Time3	Time4	Time5	Time6	Time7
Demographic data	X						
STAI A - STATE	X						X
A - TRAIT	X						
RINV	X	X	X	X	X	X	X
SCBL	>----->	>----->	>----->	>----->	>----->	>----->	

prior 12 24 36 48 60 72

posttreatment

|_____| |_____| |_____| |__

Day 1 Day 2 Day 3 Day 4

Appendix B

Adapted Dodd's Self-Care Behavior Log (SCBL)

SELF-CARE BEHAVIOR LOG
FOR NAUSEA AND VOMITING

Code # _____

DATE: /

	ACTIONS TAKEN	EFFECTIVENESS OF ACTIONS (NOT RELIEVED AT ALL 1 2 3 4 5 COMPLETELY RELIEVED)	SOURCES OF SUGGESTIONS FOR ACTIONS
1. Nausea _____ Vomiting _____ Time of onset: _____	a) Severity of Side Effect, i.e. how intense is it? barely noticeable 1 2 3 4 5 most severe b) Distress of Side Effect, i.e. how much does it bother you? minor annoyance 1 2 3 4 5 extremely distressing	a. _____ Time: ____ b. _____ Time: ____ c. _____ Time: ____ d. _____ Time: ____	a. _____ b. _____ c. _____ d. _____
2. Nausea _____ Vomiting _____ Time of onset: _____	a) Severity of Side Effect, i.e. how intense is it? barely noticeable 1 2 3 4 5 most severe b) Distress of Side Effect, i.e. how much does it bother you? minor annoyance 1 2 3 4 5 extremely distressing	a. _____ Time: ____ b. _____ Time: ____ c. _____ Time: ____ d. _____ Time: ____	a. _____ b. _____ c. _____ d. _____

Appendix C

Adapted Rhodes Index of Nausea and Vomiting (RINV)

INV-FORM 2

Directions: Draw a circle around the sentence in each row that most clearly corresponds to your experience. Please make one mark on each line.

I.D. Number_____ Date_____

Time_____ Time of C.T._____

I threw up seven or more times during the last 12 hours.	I threw up five-six times during the last 12 hours.	I threw up three-four times during the last 12 hours.	I threw up one-two times during the last 12 hours.	I did not throw up during the last 12 hours.	
During the last 12 hours I have felt as severe distress from vomiting as can be.	During the last 12 hours I have felt great distress from vomiting.	During the last 12 hours I have felt moderate distress from vomiting.	During the last 12 hours I have felt mild distress from vomiting.	During the last 12 hours I have not felt any distress from vomiting.	
I have not felt nauseated or sick at my stomach during the last 12 hours.	I have felt nauseated or sick at my stomach for one hour or less during the last 12 hours.	I have felt nauseated or sick at my stomach for two-three of the last 12 hours.	I have felt nauseated or sick at my stomach four to six of the last 12 hours.	I have felt nauseated or sick at my stomach more than six of the last 12 hours.	
During the last 12 hours I have not felt any distress from nausea/sickness as can be.	During the last 12 hours I have felt mild distress from nausea or sick at my stomach.	During the last 12 hours I have felt moderate distress from nausea or sick at my stomach.	During the last 12 hours I have felt great distress from nausea or sick at my stomach.	During the last 12 hours I have felt as severe distress from nausea or sick at my stomach.	
During the last 12 hours I produced a very large (3 cups or more) amount each time I threw up.	During the last 12 hours I produced a large (2-3 cups) amount each time I threw up.	During the last 12 hours I produced a moderate (½-2 cup) amount each time I threw up.	During the last 12 hours I produced a small (up to ½ cup) amount each time I threw up.	During the last 12 hours I did not throw up.	
I felt nauseated or sick at my stomach 7 or more times during the last 12 hours.	I felt nauseated or sick at my stomach 5-6 different times during the last 12 hrs.	I felt nauseated or sick at my stomach 3-4 different times during the last 12 hrs.	I felt nauseated or sick at my stomach 1-2 different times during the last 12 hrs.	I did not feel nauseated or sick at my stomach during the last 12 hours.	

Appendix D

State-Trait Anxiety Inventory (STAI)

STAI FORM X-1

Developed by C. D. Spielberger, R. L. Gorsuch and R. Lushene

STAI FORM X-1

CODE NUMBER _____ DATE _____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *feel* right now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	①	②	③	④
2. I feel secure	①	②	③	④
3. I am tense	①	②	③	④
4. I am regretful	①	②	③	④
5. I feel at ease	①	②	③	④
6. I feel upset	①	②	③	④
7. I am presently worrying over possible misfortunes	①	②	③	④
8. I feel rested	①	②	③	④
9. I feel anxious	①	②	③	④
10. I feel comfortable	①	②	③	④
11. I feel self-confident	①	②	③	④
12. I feel nervous	①	②	③	④
13. I am jittery	①	②	③	④
14. I feel "high strung"	①	②	③	④
15. I am relaxed	①	②	③	④
16. I feel content	①	②	③	④
17. I am worried	①	②	③	④
18. I feel over-excited and "rattled"	①	②	③	④
19. I feel joyful	①	②	③	④
20. I feel pleasant	①	②	③	④

Appendix D

State-Trait Anxiety Inventory (STAI)

SELF-EVALUATION QUESTIONNAIRE

STAI FORM X-2

CODE NUMBER _____ DATE ____ ____ ____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	(1)	(2)	(3)	(4)
22. I tire quickly	(1)	(2)	(3)	(4)
23. I feel like crying	(1)	(2)	(3)	(4)
24. I wish I could be as happy as others seem to be	(1)	(2)	(3)	(4)
25. I am losing out on things because I can't make up my mind soon enough	(1)	(2)	(3)	(4)
26. I feel rested	(1)	(2)	(3)	(4)
27. I am "calm, cool, and collected"	(1)	(2)	(3)	(4)
28. I feel that difficulties are piling up so that I cannot overcome them	(1)	(2)	(3)	(4)
29. I worry too much over something that really doesn't matter	(1)	(2)	(3)	(4)
30. I am happy	(1)	(2)	(3)	(4)
31. I am inclined to take things hard	(1)	(2)	(3)	(4)
32. I lack self-confidence	(1)	(2)	(3)	(4)
33. I feel secure	(1)	(2)	(3)	(4)
34. I try to avoid facing a crisis or difficulty	(1)	(2)	(3)	(4)
35. I feel blue	(1)	(2)	(3)	(4)
36. I am content	(1)	(2)	(3)	(4)
37. Some unimportant thought runs through my mind and bothers me	(1)	(2)	(3)	(4)
38. I take disappointments so keenly that I can't put them out of my mind	(1)	(2)	(3)	(4)
39. I am a steady person	(1)	(2)	(3)	(4)
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	(1)	(2)	(3)	(4)

Appendix E

Code # _____

Demographic Data Inventory

1. Age _____ 2. Birthdate _____/_____/_____

Month Day Year

3. Ethnic Background:

_____ (1) Taiwanese _____ (3) Hakka

_____ (2) Mandarin _____ (4) other

4.Religious preference:

_____ (1) Taoist _____ (5) Mormon

_____ (2) Buddhist _____ (6) Jewish

_____ (3) Catholic _____ (7) no preference

_____ (4) Protestant _____ (8) other

5. Marital Status:

_____ (1) Single, never married

_____ (2) Married

_____ (3) Divorced or separated

_____ (4) Widowed

6. Living arrangement:

_____ (1) Alone

_____ (2) With spouse or partner

_____ (3) With family

_____ (4) other

(Demographic Data Inventory continued)

7. Highest grade in school completed:

___ (1) Up to 6th grade ____ (4) Some college

___ (2) Junior high school____ (5) College graduate

___ (3) Senior high school

___ (6) Other, please specify_____

8. Occupation (If retired, former occupation)_____

9. Date of cancer diagnosis_____

10. Specific cancer diagnosis _____

11. Stage of disease __ (1) limited __ (2) advanced.

12. Medical diagnosis other than cancer _____

13. Date chemotherapy due to start_____

14. Type(s) and date(s) of previous or current chemotherapy (include name of drugs, routes of administration _____

_____

15. Type(s) and date (s) of previous or current surgery for this illness_____

_____

16. Type(s) and date(s) of previous or current radiation therapy_____

_____

17. Other medications (excluding chemotherapy) you are taking_____

(Demographic Data Inventory continued)

18. Is the purpose of your receiving treatment to cure the disease? _____ Yes _____ No _____ not sure

    To shrink the tumor?

    _____ Yes _____ NO _____ not sure

19. Has anyone in your family or close friends had cancer?

    _____

20. If yes, 1) who? _____

    2) type of cancer? _____

    3) type of treatment used?_____

    4) How are they now?_____

21. Your performance status at the time of the interview:

    _____ 90-100 Full active, able to carry on all predisease performance without restriction.

    _____ 70-89 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.

    _____ 50-69 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

    _____ 30-49 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

    _____ 10-29 Completely disables. Cannot carry on any self-care. Totally confined to bed or chair.

Appendix F

Code # ____

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

SCHOOL OF NURSING

CONSENT TO BE A RESEARCH SUBJECT

PURPOSE AND BACKGROUND:

Marylin J. Dodd R.N. Ph.D.(Associate Professor and (Chairperson) and Li-Hua Lo R.N.(M.S.student) are conducting a study to better understand the patterns of self-care behaviors for nausea and vomiting from chemotherapy. I have been asked to participate in this study.

PROCEDURES:

If I agree to be in this study, the following will occur:

First, one of investigator (Li-Hua Lo) will assess my anxiety level, the severity of nausea and vomiting and personal background by filling out three kinds of questionnaires before the chemotherapeutic treatment begins. Second, she will explain to me how to record my nausea and vomiting and strategies which can release it on self-care behavior log. Third, after the chemotherapeutic treatment begins, she will mark the exact time on the questionnaires and let me know when and how to complete them. I will report the severity of nausea and vomiting at a 12-hour interval after chemotherapy for 72 hours. Finally, in the Day-4 morning after chemotherapy I will complete all of the

(Consent continued)

questionnaires and put them into an envelop the investigator has prepared, and mail it to her.

RISKS/DISCOMFORTS:

1. Because you are requested to report your nausea and vomiting several times over a 72 hour period, you may feel discomfort or fatigue and are free to decline to answer any questions on the questionnaires.
2. Confidentiality: My records will be handled as confidentially as is possible within the law. Only an identification number will appear on all of the questionnaires. If the results of this study are published in scientific journals, my identity will not be disclosed.

BENEFITS:

Whether the study will directly benefit me is not known. I may enjoy the opportunity to discuss my background and experiences about the nausea and/or vomiting. In addition, my participation will help nurses and physicians to better understand some of the effects of the cancer treatment.

QUESTIONS:

I have discussed this information with Nurse Li-Hua Lo and my questions were answered. If I have any further questions at home, I may contact her at (02)341-4126.

CONSENT:

I have been given a copy of this form and the Experimental Subject's Bill of Rights to keep. If I have any comments about participation in this study, I should first talk with the investigator. If for some reason I do not wish to do this, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office between 8 and 5, Monday to Friday, by calling (415)476-1814, or by writing: Committee on Human Research/Box 0616/University of California, San Francisco/San Francisco, CA 94143. PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to participate or to withdraw at any point in this study without jeopardy to my medical care. If I wish to articipate I should sign this form.

_____ _____

Date Subject's signature

==========

The person being considered for this study is unable to consent for himself/herself. I have been asked to give my permission to include my relative in this study. I know of no reason why he/she would refuse were it possible to do so now.

_____ _____

Date Relative´s signature

_____

Relationship

Appendix G

UCSF, Experimental Subject's Bill of Rights

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) **To be told what the study is trying to find out,**

2) **To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,**

3) **To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes,**

4) **To be told if I can expect any benefit from participating, and, if so, what the benefit might be,**

5) **To be told the other choices I have and how they may be better or worse than being in the study,**

6) **To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,**

7) **To be told what sort of medical treatment is available if any complications arise,**

8) **To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.**

9) **To receive a copy of the signed and dated consent form,**

10) **To be free of pressure when considering whether I wish to agree to be in the study.**

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, University of California, San Francisco, CA 94143.

Call X1814 for information on translations.

12/ 1/78

Appendix H

Letter to Dr. Rhodes

500 Parnassus Ave. #421W
San Francisco, CA 94143
March 12, 1987

Verna A. Rhodes, RN, MEd, EdS.
School of Nursing
S314 Stadium Road,
Columbia, MO 65211

Dear MS. Rhodes,

I am a first-year graduate student in University of California, San Francisco. This quarter I study research methodology and write a research proposal using your "Rhodes Index of Nausea and Vomiting Scale" to assess breast cancer patients' nausea and vomiting induced by chemotherapy. Now, I want to get your permission to use this tool, then I will translate into Chinese to collect data in my country, Taiwan, the Republic of China. Hope to hear your answer soon. Thanks a lot.

Warmest Regards,

Li - Hua Lo

Li - Hua Lo

Appendix I

Permission letter from Dr. Rhodes

UNIVERSITY OF MISSOURI-COLUMBIA

SCHOOL OF NURSING

S235 Nursing School Building
Columbia, Missouri 65211
Telephone (314) 882-0226

March 17, 1987

Ms. Li-Hua Lo
500 Parnassus Avenue #412W
San Francisco, CA 94143

Dear Ms. Lo:

In response to your letter of March 12, 1987, requesting the use of the "Rhodes Index of Nausea and Vomiting" for your study of post-chemotherapy nausea and vomiting in patients with breast cancer, I am enclosing a copy of the INV Form 2 as well as an order form for the Rhodes INV Form 2. Each packet of INV forms include instructions for administering, scoring and a bibliography.

I understand that you are a graduate student at the University of California in San Francisco and that you plan to translate the INV into Chinese to collect data in your country, Taiwan, the Republic of China. I am pleased to give my permission and will be most interested in your data. Proper citation of the instrument's authorship, reliability and validity is expected, as well as information regarding your progress and a copy of your data.

If you have any questions regarding the use of the instrument, contact me at (314) 882-0226.

Sincerely,

Verna A. Rhodes, RN, EdS
Assistant Professor

VAR/cjh

Appendix J

Support letter from Dr. Dodd

...ol of Nursing
...artment of Physiological
... N-1"Y Box 0610
... CA 94143

UCSF
University of California, San Francisco . A Health Sciences Campus

April 21, 1987

Hospital Administrator
Chang Gung Memorial Hospital

Dear Sir:

I am writing this letter of support for Li-Hua Lo who is currently a graduate student in nursing at the University of California, San Francisco. I am her faculty advisor for a research project she wishes to conduct at your hospital. The title of the project is "Assessing Patients' Pattern of Self-care Behaviors for Nausea and Vomiting from Cancer Chemotherapy." I have reviewed this project proposal and believe it to be scientifically sound and nonoffensive to your patients. The patients will be asked to report their nausea and vomiting during one cycle of their chemotherapy. The patients' identity in the project will not be revealed in the project report.

I appreciate any assistance you can give Li-Hua Lo in obtaining access to your patients for her project.

Sincerely,

Marylin J. Dodd

Marylin J. Dodd, R.N., Ph.D.
Associate Professor and
Interim Chairperson

MJD/ian
ADMINC:M421

Appendix K

Initial Short-Form application to UCSF

Committee on Human Research

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
COMMITTEE ON HUMAN RESEARCH

INITIAL SHORT-FORM APPLICATION
Submission Date Apr. 16'87

Principal Investigator (UCSF Faculty) Dodd, Marylin J. R.N., Ph.D. University Title Associate Professor and Chairperson Dept. Physiological Nursing
P.I. Mailing Address (campus if possible) School of Nursing, N611N
P.I. Phone No. (415) 476-4320
Co-Investigator and Title Lo, Li-Hua M.S. student
Is the principal investigator the sponsor/advisor only? Yes X No
Co-P.I. Mailing Address 500 Parnassus Ave. #412W San Francisco, CA 94143
Co-P.I. Phone No. (415) 566-0176
Project Title Assessing Patients' Patterns of Self-Care Behaviors for Nausea and Vomiting from Cancer Chemotherapy

INSTRUCTIONS: PLEASE TYPE; SUBMIT
-4 COPIES OF THIS TWO-PAGE FORM
-4 COPIES OF ANY ATTACHMENTS (CONSENT FORMS, QUESTIONNAIRES, ETC.)
To be safe, allow at least 4 weeks for processing.

A) The point of this project is (Explain background, rationale, hypothesis, basic design, etc.):
The purpose of this longitudinal study using a level I descriptive exploratory research design is to identify the patterns of self-care behaviors for episodes of nausea and/or vomiting in two groups of outpatients with breast cancer undergoing cycle 1 chemotherapy or cycle two and more within the first six months of an initial chemotherapy regimen.

B) The subject population(s) will be selected (or excluded) on the following criteria (Discuss how access will be gained as well as any problems relevant to special subject populations):

(1) 18 years or older, (2) mentally and physically competent, (3) able to speak and read Chinese, (4) diagnosed as having breast cancer, (5) scheduled to begin a course of chemotherapy within the first six months of an initial chemotherapy regimen, and (6) patient must experience nausea or vomiting to be able to complete the self-care behavior log.

C) The following procedures involving humans will be done for purposes of the study (If applicable, include interview themes and questionnaires if not commonly known): If the patient consents, the demographic data will be completed by an interview. The patient will be asked to respond to the RINV (Time 1), and the STAI (Time 1) before the chemotherapy treatment begins (see Time table for study). Then, the investigator will give patient a package of questionnaires including the RINV sheets, State Anxiety Scale and the SCBL; and explain how and when to complete each of them.

CHR SHORT-FORM APPLICATION
Page 2

Investigator: Lo, Li-Hua

D) **The risks involved in these procedures and the methods of minimizing the risks, inconveniences, or discomforts are (Include any potential for loss of privacy):**

There are no known risks to subjects in this study.

E) **Describe the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result:**

Whether the study will directly benefit subjects is not known. The result of this study will help nurses and physicians to better understand some of the effects of the cancer treatment.

F) **Describe the consent process and attach all consent documents. If waiver from use of written consent is requested, give the justification.**

The consent form and the measuring instruments will be translated into Chinese and established content validity by two nurse clinical oncology specialists in Taiwan who graduated from UCSF. The investigator will approach each potential participant to give his/her verbal and written information about the study and get the consent.

G) **The number of subjects to be enrolled per year:** 60 **Total for study:** 60 .

H) **The expedited review category number from** Consent Forum, **Issue 5, is** 13 .

Appendix L

Letter from UCSF, Committee on Human Research

PROTECTION COMMITTEES, BOX 0616
OFFICE OF RESEARCH AFFAIRS
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

May 22, 1987

Li-Hua Lo
Department of Physiological Nursing
Mu-412-W

Dear Ms. Lo:

During the meeting of May 7, the Human Research sub-committee reviewed your application, "Assessing Patients' Patterns of Self-Care Behaviors for Nausea and Vomiting from Cancer Chemotherapy." The members agreed that the protocol could be approved contingent on your response to several points.

First, the application does not state where this study is being conducted, nor does it give information concerning recruitment. That is, further discussion of where, how and by whom will possible subjects be approached should be included in the response.

Second, several changes were requested in the consent form:

1) It was asked if the consent form was going to be translated into Chinese and if if is will be printed in Chinese, the Committee would like a copy of this translation on file.

2) The first three sections of the consent form should be labeled, as are the last three. A sample UCSF consent form is enclosed for your reference.

3) The first paragraph of the consent form should also include the name of the principal investigator.

3) The members agreed that the Procedures description could be made clearer by revising it as follows:

a) The procedures should be listed (first, second, third).
b) The subjects should be told what the questionnaires are about rather than being given the technical names.
c) As it would be assumed that subjects answer the questionnaires "honestly and conscientiously" at home, these modifiers should be deleted.
d) Paragraph C should be either be in the Procedures section or in its own labeled section.

4) In studies involving interviews and/or questionnaires, the risks discussion usually mentions the possible inconvenience of taking part, and the risk of some of the questions making the individual uncomfortable or upset. Your risks discussion should include these points and note that the person is free to decline to answer any questions at any time. In addition, because of the length of the time it would take to answer these questions, the discomfort or risk of fatigue should be added to this discussion.

5) Because of the addition of the name of the principal investigator, the Questions section should be revised slightly to read as follows: "I have discussed this information with Nurse Li-Hua Lo and my questions were answered. If I have any further questions, I may contact her at (415) 566-0176."

Ms. Li-Hua Ho
May 22, 1987
page 2

6) While California law requires that the Experimental Subject's Bill of Rights be given only to subjects of biomedical research, there is contact information contained in the UCSF Bill of Rights which should be given to all subjects. Thus, it was requested that either the Bill of Rights be given to each participant, or that the following paragraph be included in the consent form:

> If I have any comments about participation in this study, I should first talk with the investigator. If for some reason I do not wish to do this, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office between 8 and 5, Monday to Friday, by calling (415) 476-1814, or by writing: Committee on Human Research/Box 0616/University of California, San Francisco/San Francisco, CA 94143.

As an aside, we are in the process of updating our telephone numbers to reflect the "476" prefix; thus, the enclosed versions of the UCSF Experimental Subject's Bill of Rights, which now provides the current, correct CHR telephone number, should be given to all subjects. We are enclosing both English and Chinese versions of the form.

Please submit four copies of your response and revised consent form to Box 0616. When these have been received and accepted, final approval will be issued. Any unaccepted consent forms in your files should be destroyed to prevent their accidental use. If you have any questions, please call the office of the Committee on Human Research at extension 6-1814.

Sincerely,

Barry Engelstad

Barry L. Engelstad, M.D.
Vice Chairman
Committee on Human Research

SKF
Enc. Experimental Subject's Bill of Rights (English and Chinese versions)
UCSF Sample Consent Form

cc: Dr. Marilyn J. Dodd
Department of Physiological Nursing
Box 0610

Appendix M

Response letter to Committee on Human Research

Department of Physiological Nursing
MU-41[illegible]

May 29,1987

RESPONSE TO COMMITTEE ON HUMAN RESEARCH

Dr. Barry L. Engelstad
Vice Chairman
Committee on Human Research

Dear Dr. Engelstad:

I would like to thank you and all your committee members for reviewing my research proposal and giving me so many valuable suggestions. I really appreciate it.

Following your guidelines the consent form has been revised and had been translated into Chinese. Answering your first comment as following:

Sorry for not describing clearly about research setting and subjects.

This study will be conducted at oncological outpatient clinic in Chung Gung Memorial Hospital (CGMH), Taiwan, the Republic of China during summer quarter (June 20 to September 10, 1987). CGMH is a large (1500-bed) private teaching hospital in the Northern of Taiwan. The investigator (Li-Hua Lo) had been in charge of in-service training program as supervisor in CGMH from August 1984 to August 1986 and will approach the potential subjects directly and individually. The subjects had been diagnosed as breast cancer and receiving chemotherapeutic treatment.

If you have further question please feel free to contact with me. Thank you anyway.

Sincerely,

Li-Hua Lo

Li-Hua Lo, R.N.

Enc. Consent to be a Research Subject (English and Chinese versions)

cc. Dr. Marilyn J. Dodd
Department of Physiological Nursing
Box 0610

Appendix N

The UCSF Committee on Human Research approved letter

DIVISION OF HUMAN & ENVIRONMENTAL
PROTECTION COMMITTEES, BOX 0616
OFFICE OF RESEARCH AFFAIRS
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

TO: Marylin Dodd, Ph.D. / Hi-Hua Lo, R.N.
Box 0610 / MU-412-W

RE: Assessing Patients' Patterns of Self-Care Behaviors for Nausea and Vomiting from Cancer Chemotherapy

The UCSF Committee on Human Research (an IRB holding DHHS assurance #M-1169) has approved the above request to involve humans as research subjects.

APPROVAL NUMBER: 941227-01* **This number is a UCSF CHR number which should be used on all consent forms, correspondence and patient charts.**

APPROVAL DATE: June 10, 1987 **Full review** X
Expedited review _____

EXPIRATION DATE: June 10, 1988 **If the project is to continue, it must be renewed by the expiration date. If the number has an asterisk, the short-form renewal process may be used.**

SUBMISSION ADDENDA: No_____ **Yes** X **A yes indicates that there was correspondence between the Committee and the investigator during review of this submission.**

CONDITIONS:

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within five working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

LEGAL NOTICE: The University will defend and indemnify a principal investigator in legal actions arising from research activities involving humans only if the activities had current CHR approval.

QUESTIONS: Please contact the Human and Environmental Protection Committees office at (415) 476-1814 or campus mail stop, box 0616.

Sincerely,
Carol S. Viele PhD RN

Carol S. Viele, R.N., M.S.
Chairman
Committee on Human Research

cc: Contracts and Grants
Drug Info and Analysis Service
SFGH_____
VAMC Research Office_____

Appendix N

The UCSF Committee on Human Research approved letter

GENERAL INFORMATION

1) CERTIFICATION:

Many funding agencies require notice that the institution is willing to assume primary responsibility for review of protection of human subjects. For federal funding, this is accomplished by submitting the DHHS Form 596 with the grant application.

UCSF will assume primary responsibility if it can be determined that all involvement of humans as subjects in the research work has received CHR approval.

-- The Contracts and Grants Approval form must be correctly completed. It must refer to the appropriate CHR approval, and a copy of the approval letter must be attached.

-- The Form 596 is available in grant packets and in Contracts and Grants. The PI should complete it, using the information on the CHR approval letter, and submit it to be signed by the Institutional Officer, who is in Contracts and Grants.

2) PAYMENT OF SUBJECTS:

Purchasing will issue blanket requisition numbers. The General Requisition should cite the following information:
-- a copy of the approval letter;
-- the approved rate for each class of subjects and/or each procedure, or
-- the protocol page clearly stating the rates; and
-- a copy of the consent form showing the pay agreement.

With a blanket number, Form 5's can be submitted to Accounting. The Form 5 should include:
-- the blanket number;
-- the subject's name and address for mailing*;
-- the subject's social security number*.

* Use of names and social security numbers create a confidentiality problem. This should be addressed in the protocol. Alternatives such as mailing to office are encouraged.

3) COPIES OF PROTOCOLS:

Extra copies of protocols are returned following review. Please note that 4 copies of the protocol or a good abstract are required for continuing review.

4) EXPIRATION DATE:

On the front of this form, an expiration date is given. It is the investigator's duty to be aware of the expiration date and to initiate renewal sufficiently early. As a courtesy, the CHR office will send a reminder about 3 to 4 weeks in advance. 3 WEEKS MINIMUM SHOULD BE ALLOWED TO RENEW APPROVALS.

Appendix O

Permission report to Chang Gung Memorial Hospital

in Chinese

簽呈

美國加州大學洛杉磯分校
一九八七年五月十八日

事由：擬徵得貴院方同意在腫瘤科門診蒐集論文研究資料，

說明：

一、敝人魏麗華曾於一九八五年八月至一九八六年八月任職貴院擔任護理人員的在職教育工作二年。現留職停薪三年在美國加州大學洛杉磯分校護理研究所進修碩士學位，主修腫瘤護理。

二、為符合完成碩士學位論文研究設計，主題是「評估癌症病患接受化學療法後發生噁心與嘔吐的自我照顧行為」（附件一）。

三、計劃於暑假期間（六月十七日至九月十日）回台蒐集論文研究資料，並已獲指導教授的支持（附件二）。

四、依院方之規定，已將問卷調查之內容翻成中文，包括小字研究同意書、基本資料記錄表、情緒量表、病房量表、噁心與嘔吐量表、自我照顧行為記錄表等（附件三），並已進行申請部分之內容教度中。

五、敬請腫瘤科主任、醫教會與院長室，能惠予同意與支持，在腫瘤科門診蒐集資料。

謝謝。

腫瘤科
醫教會
院長室

魏麗華

自我照顧行爲記錄表

編號：_____

由化學療法引起的副作用		採取的行動	所採行動的有效程度（一點都沒有效 1 2 3 4 5 非常有效）	是誰建議採取這行動
1. _____	(甲)有多嚴重？ 做能察覺 極嚴重 1 2 3 4 5	甲. _____ 時間：_____	1 2 3 4 5	甲. _____
發生的時間：_____ 上午 下午		乙. _____ 時間：_____	1 2 3 4 5	乙. _____
		丙. _____ 時間：_____	1 2 3 4 5	丙. _____
	(乙)有多痛苦？即此副作用困擾您的程度？ 極少痛苦 非常痛苦 1 2 3 4 5	丁. _____ 時間：_____	1 2 3 4 5	丁. _____
2. _____	(甲)有多嚴重？ 做能察覺 極嚴重 1 2 3 4 5	甲. _____ 時間：_____	1 2 3 4 5	甲. _____
發生的時間：_____ 上午 下午		乙. _____ 時間：_____	1 2 3 4 5	乙. _____
		丙. _____ 時間：_____	1 2 3 4 5	丙. _____
	(乙)有多痛苦？即此副作用困擾您的程度？ 極少痛苦 非常痛苦 1 2 3 4 5	丁. _____ 時間：_____	1 2 3 4 5	丁. _____
3. _____	(甲)有多嚴重？ 做能察覺 極嚴重 1 2 3 4 5	甲. _____ 時間：_____	1 2 3 4 5	甲. _____
發生的時間：_____ 上午 下午		乙. _____ 時間：_____	1 2 3 4 5	乙. _____
		丙. _____ 時間：_____	1 2 3 4 5	丙. _____
	(乙)有多痛苦？即此副作用困擾您的程度？ 極少痛苦 非常痛苦 1 2 3 4 5	丁. _____ 時間：_____	1 2 3 4 5	丁. _____

Permission to translate this questionnaine given by Marylin J. Dodd.

羅氏噁心嘔吐量表

編號：_____

說明：在每一列中圈出一個與您的經驗最相近的句子

日期：_____

請在每一列中，只圈出一個句子

時間：_____上午、下午

過去的12小時中，我嘔吐7次或7次以上	過去的12小時中，我嘔吐5～6次	過去的12小時中，我嘔吐3～4次	過去的12小時中，我嘔吐1～2次	過去的12小時中，我沒有嘔吐
過去的12小時中，嘔吐讓我感到極度痛苦	過去的12小時中，嘔吐讓我感到非常痛苦	過去的12小時中，嘔吐讓我感到中度痛苦	過去的12小時中，嘔吐讓我感到輕度痛苦	過去的12小時中，嘔吐並未令我感到痛苦
過去的12小時中，我沒有噁心或胃不舒服的感覺	過去的12小時中，我感覺噁心或胃不舒服少於1小時	過去的12小時中，有2～3小時我感到噁心或胃不舒服	過去的12小時中，有4～6小時我感到噁心或胃不舒服	過去的12小時中，至少6小時以上我感覺噁心或胃不舒服
過去的12小時中，噁心並未令我感到痛苦	過去的12小時中，噁心或胃不舒服令我感到輕度的痛苦	過去的12小時中，噁心或胃不舒服令我感到中度的痛苦	過去的12小時中，噁心或胃不舒服令我感到非常痛苦	過去的12小時中，噁心或胃不舒服令我感到極度痛苦
過去的12小時中，每次我嘔吐極大量（3杯以上）	過去的12小時中，每次我嘔吐大量（2～3杯）	過去的12小時中，每次我嘔吐中量（半杯到2杯）	過去的12小時中，每次我嘔吐小量（不到半杯）	過去的12小時中，我並未嘔吐
過去的12小時中，我感到噁心或胃不舒服7次以上	過去的12小時中，我感到噁心或胃不舒服有5～6次	過去的12小時中，我感到噁心或胃不舒服有3～4次	過去的12小時中，我感到噁心或胃不舒服1～2次	過去的12小時中，我並未感到噁心或胃不舒服

Appendix R

STAI in Chinese

A-State

情境量表

編號：

日期：

說明：以下諸句子是人們用來描述自己。閱讀每一個句子，並在右邊圈出適當的數字，表示此刻即現在您的感受。沒有對或錯的回答，不要花太多時間在任何一句上，但所圈的答案似最能描述您現在的感受爲原則。

	一點都不	有一點	偶爾如此	經常如此
1.我感到平靜、安祥	1	2	3	4
2.我感到安全	1	2	3	4
3.我緊張	1	2	3	4
4.我懊悔	1	2	3	4
5.我感到輕鬆	1	2	3	4
6.我生氣	1	2	3	4
7.我現在擔心可能有不祥的事發生	1	2	3	4
8.我想要休息	1	2	3	4
9.我感到焦慮	1	2	3	4
10.我感到舒適	1	2	3	4
11.我感到自信	1	2	3	4
12.我感到緊張	1	2	3	4
13.我感到心神不定、恐慌	1	2	3	4
14.我感到易興奮	1	2	3	4
15.我處於鬆弛狀態	1	2	3	4
16.我感到滿足	1	2	3	4
17.我擔心著	1	2	3	4
18.我感到過於激動並喋喋不休	1	2	3	4
19.我覺得高興	1	2	3	4
20.我覺得愉快	1	2	3	4

Developed by C.D.Spielberger, R.C.Gorsuch and R. Lushene
Permission to translate this guestionnaire given by Charles D. Spielberger.

Appendix R

STAI in Chinese

A-Trait

特 質 量 表

編號：＿＿＿

日期：＿＿＿

說明：以下諸句子是人們用來描述自己，閱讀每一個句子，並在右邊圈出適當的數字，表示此刻即現在您的感受。沒有對或錯的回答。不要花太多時間在任何一句上，但所圈的答案似最能描述您現在的感受爲原則。

	一點都不	有一點	偶爾如此	經常如此
21.我感到很愉快	1	2	3	4
22.我很快即厭煩疲倦	1	2	3	4
23.我想要哭	1	2	3	4
24.我期望像別人一樣快樂	1	2	3	4
25.因我不能很快的作決定，所以失去機會	1	2	3	4
26.我想要休息	1	2	3	4
27.我現在很安詳、冷靜且精神集中	1	2	3	4
28.我感覺困難重重，不能克服	1	2	3	4
29.我太擔心一些並不眞嚴重的事	1	2	3	4
30.我感到快樂	1	2	3	4
31.我喜好把事情看得很嚴重	1	2	3	4
32.我缺乏自信	1	2	3	4
33.我感到安全	1	2	3	4
34.我試著避免面對危機情況或困難	1	2	3	4
35.我覺得憂鬱	1	2	3	4
36.我感到滿足	1	2	3	4
37.一些不重要的事縈繞心頭並困擾我	1	2	3	4
38.失望、挫折深深地困擾我，以致於不能從心頭排除	1	2	3	4
39.我是個穩重的人	1	2	3	4
40.當我考慮我最近關心的一些事和興趣時，我感到緊張或混亂	1	2	3	4

Developed C.D.Spielberger, R.L.Gorsuch and R.Lushene

Permission to translate this questionnaire given by Charles D. Spielberger.

Appendix S

Demographic Data Inventory in Chinese

病患基本資料記錄表　　編號：____

1.性別：男____女____　　1.□

2.年齡_____歲　3.出生年月日：____年____月____日　　2.3.□□　4.5.□□　6.7.□□　8.9.□□

4.籍貫：_____

5.宗教信仰：_____(1)佛教_____(2)基督教_____(3)天主教　　10.□

_____(4)道教_____(5)摩門教_____(6)猶太教　　11.□

_____(7)沒特別信仰 __ (8)其他_____

6.婚姻狀況：_____(1)單身、未婚_____(2)已婚_____(3)離婚或分居　　12.□

_____(4)鰥、寡

7.生活狀況：_____(1)獨居_____(2)與配偶同住____(3)與家人同住

_____(4)同居人_____(5)其他_____　　13.□

8.教育程度：(1)不識字　(2)小學 1 2 3 4 5 6

(3)初中 1 2 3　(4)高中 1 2 3　　14.□ 15.□

(5)五專 1 2 3 4 5　(6)三專 1 2 3

(7)大學 1 2 3 4　(8)研究所 1 2 3 4

9.職業（若退休，以前的職業）_____　　16.□

10.診斷確定的日期：_____年_____月_____日　　17.18.□□ 19.20.□□ 21.22.□□

11.診斷：_____　　23.□

12.疾病的期別：(1)局部_____(2)已轉移_____　　24.□

13.除癌症以外的診斷：_____　　25.□

_____

14.治療開始的日期：_____年_____月_____日　　26.27.□□ 28.29.□□ 30.31.□□

15.以前或現在化學治療的種類與期間（包括藥名、途徑）

_____

_____

Appendix S

Demographic Data Inventory in Chinese

16.以前或現在手術的種類和日期

_____

17.以前或現在接受放射線治療的種類和期間

_____

_____

18.曾用過的其他藥物（不包括化學療法）

_____

_____

19.接受這次的治療，其目的是要治癒您的病嗎？ 32. □

是___否___不確定 _____

是要縮小腫瘤的大小嗎？ 是___否___不確定 _____ 33. □

20.您的家人、親戚或好友是否有誰罹患癌症？是___ 否_____ 34. □

21.若有，(1)是誰？_____

(2)是那種癌症？_____

(3)曾接受何種治療？_____

(4)他現在的情況如何？_____

22.會談時您的身體狀況： 35.36. □□

_____90～100 活動自如，能做所有患病前的活動，沒有任何限制。

_____70～89 耗費體力的活動受限制，但可下床活動自如，完成輕度工作或久坐的工作，如輕微家事、辦公。

_____50～69 能下床活動及自我照顧，但不能完成任何工作。有一半以上清醒的時間是下床活動的。

_____30～49 只能完成有限的自我照顧，一半以上清醒的時間被限制在床上或椅子上。

_____10～29 完全不能完成任何自我照顧，完全被限制在床上或椅子上。

Appendix T

Consent Form in Chinese

美國加州大學舊金山分校，護理研究所

參與研究同意書　　編號：_____

目的與背景：

Dr. M. J. Dodd（指導教授）與駱麗華（碩士研究生）共同主持這研究，爲了瞭解病患接受化學療法後引起的噁心與嘔吐，病患自我照顧的模式，她們邀請我參與這研究。

研究步驟：

假若我同意參與這研究，以下事項將會發生：

1.在化學治療開始之前，研究者之一，駱麗華研究生將評估我的焦慮程度，噁心與／或嘔吐的情形，及我的背景資料與治療經過。

2.接著她將解釋如何使用自我照顧行爲記錄表，隨時記下我不舒服的現象與如何解除的方法。

3.化學藥物治療開始後，她將把正確的時間一一填在表格上，並讓我知道何時及如何去完成它。化學治療開始後每12小時，我將記錄一次噁心與嘔吐的情形在羅氏噁心與嘔吐量表上，共72小時。

4.在最後一次記錄羅氏量表的同時（即治療開始後的第四天早上）我將再完成一次情境量表，以與化學治療開始前作比較。此時我已完成所有的表格，並把它們放在研究者事先已準備好的信封中，寄給她。

危險性與不適：

1.因此研究需記錄化學治療後72小時內發生的情形，當我記錄這些表格時，或許會覺得不舒服或疲倦，假若我實在無法作答，研究者將不介意。

2.機密性：我所作的任何記錄，將儘可能的保守機密，只有編號會在表格上。若此研究結果將發表在科學性的雜誌上，我的姓名將不被洩露。

裨益：

本研究是否對我有直接的裨益尚不知，但我可能有機會討論我的治療經過與所經驗的噁心和／或嘔吐。此外，參與本研究我將幫忙護士和醫師對癌症治療的效果瞭解更清楚。

Appendix T

Consent Form in Chinese

（參與研究同意書）

問題：

我已和研究者之一駱麗華護理師討論這些資料，並獲解答。若回到家，我發現任何其他的問題，我可以打電話詢問她，電話號碼是(02)341-4126。

同意書：

研究者已給我一份「參與研究同意書」與「加州大學（三藩市）被實驗者的權利」。參與此研究，若我有任何意見，我將先告訴研究者。若基於某些理由，我不願如此做時，我可以跟加州大學人類研究委員會聯絡。該委員會關注保護參與研究計劃的義務人員。我可以於週一至週五上午八時至下午五時，致電該委員會。電話(415)476-1814或寫信，地址：三藩市加州大學人類研究委員會，郵區號碼：94143。

參與此研究是出於自願：

我可以在任何時候拒絕或退出此研究，而不影響我的醫療照顧。若我願意參與此研究，我將簽署此同意書。

_____ _____

日期 參與者簽名

==========

我是參與者的家屬。我被要求同意我的家人參與此研究，我沒有理由知道他／她爲什麼拒絕如此做。

_____ _____

日期 親屬簽名

_____

與參與者的關係

Appendix U

UCSF, Bill of Right in Chinese

加州大學（三藩市）被實驗者的權利

任何人被要求參與實驗研究，擁有下列權利。作爲被實驗者，我有以下的種種權利：

（一）得告訴我研究的目的是什麼。

（二）得告訴我實驗對我會有什麼後果。實驗過程，所服用的藥物，及處理方法和標準一般有何不同。

（三）得告訴我因研究而會帶給我的經常性的危險及或重要的危險，副作用，及不妥。

（四）得告訴我如果參與實驗，有沒有任何福利。如果有，有什麼福利。

（五）得告訴我有沒有其他的選擇。這些選擇，與實驗研究比較，是更好或更壞。

（六）有權在研究之前，或研究進行期間，提出與研究有關的問題。

（七）得告訴我如果有任何併發症出現，有什麼醫藥治療適用。

（八）於研究開始後，可以拒絕參與，或改變主意。任何決定並不影響我應得到的照顧的權利，即使我不再參與研究。

（九）得發給我一張有簽署及日期證明的同意表格。

（十）在考慮參不參加實驗研究時，不得有任何壓力左右我。

如果我有問題，我應向研究員或研究助理詢問。除此之外，我可以跟人類研究委員會聯絡。該委員會關注保護研究計劃的義務人員。我可以於週一至週五上午八時至下午五時，致電該委員會。電話（四一五）四七六－一八一四。或寫信，地址：三藩市加州大學人類研究委員會，郵區號碼：九四一四三，

對謝謝資料有問題者，請電內線一八一四。

七八年十二月一日