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POST-DISCHARGE SEROMA FORMATION FOLLOWING BREAST CANCER SURGERY: IMPLICATIONS FOR THE ADVANCED PRACTICE NURSE

By

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ABSTRACT

POST-DISCHARGE SEROMA FORMATION FOLLOWING BREAST CANCER SURGERY: IMPLICATIONS FOR THE ADVANCED PRACTICE NURSE

By

Mary J. Bloomfield

Medical management of breast cancer patients in the United States has changed dramatically in recent years, largely in response to rising health care costs. A variety of surgical procedures are available, including the traditional modified radical mastectomy and new, breast-conserving techniques. Hospital stays of 24 hours or less have become the norm, and patients are expected to perform more self-care actions during their recovery at home. Among these actions is recognition of surgical complications, the most common being seroma formation, a potentially infectious accumulation of fluid in the surgical site. The etiology of seroma is unknown, and prevention is problematic.

Results of this secondary analysis of the federal grant, *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325), Gwen Wyatt, RN, PhD, Principle Investigator, suggest that women undergoing traditional surgery were at five times greater risk for seroma formation compared to women receiving breast-conserving surgery, regardless of the type of post-discharge care they received, or personal characteristics such as body mass index or age. Implications for the Advanced Practice Nurse (APN) on the interdisciplinary team include educating patients about seroma formation, facilitating self-care, and collaborating with tertiary providers in order to prevent serious sequella.

This study is dedicated in memory of my mother, Marion Bloomfield.

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Introduction

Statement of the Problem

In response to rising health care costs, surgical management of breast cancer patients has changed dramatically in recent years. Hospital stays of 24 hours or less have become the norm, and patients are increasingly expected to engage in self-care actions during their recovery period at home (Clark & Kent, 1997; Kambouris, 1996). These actions include monitoring for post-surgical complications.

The most frequent complication after breast cancer surgery is seroma formation. Although not as serious a complication as frozen shoulder or lymphedema, the problem of seroma formation is worthy of study by the Advanced Practice Nurse (APN) in the current health care environment. A seroma is fluid that accumulates in surgical dead space which creates a suitable culture medium for retrograde skin bacteria in the presence of a foreign body, such as a drain. Infection and sepsis can result as long as the drain remains intact. If the drain is removed prematurely, a seroma may form, and must be treated with one or more percutaneous aspirations, reinsertion of a drain, or open drainage by lancing. The possible etiologies of seroma formation are unknown.

Data from the federal grant, *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) (Wyatt, Given, & Given, 1995), were used to analyze a collection of risk factors associated with seroma formation. Begun in 1996, the parent study was a four-year federally funded nursing intervention program that sought to determine the type of care women needed at home after short-stay surgery, and taught women how to care for themselves post-discharge.

Shortened hospital stays mandate that patient care be performed by the patient and/or family caregivers. The APN is uniquely qualified to facilitate patient self-care. As part of an interdisciplinary health care team planning post-discharge care, the APN provides continuity of care throughout the disease process by collaborating with other health care providers.

As a primary care provider, the APN screens patients for breast cancer is the first health care provider to educate patients about self care needs. In the event that breast cancer is found, the APN in primary care provides preliminary teaching about the disease process and treatment options, and refers patients to tertiary care providers.

As part of the interdisciplinary health care team planning post-discharge care, the APN is concerned with post-surgical complications, the most common being seroma formation. Seromas usually occur one to four weeks after the patient has been discharged from the hospital (Clark & Kent, 1992; Holcombe, West, Mansel, & Horgan, 1995; Burak, Goodman, Young, & Farrar, 1997). Unless the seroma is recognized and treated promptly, it can become infected, interfere with wound healing, delay adjuvant cancer therapy, and increase patient discomfort and health care costs. For the APN, knowledge about possible risk factors for seroma will improve the quality of patient education, thereby facilitating optimal self-care throughout the disease process.

The nursing protocol administered to women in the intervention arm of the parent study took place during the first two weeks after surgery. Nurses instructed patients to engage only in light activities of daily living while the drain was intact, and to measure and record drainage output daily. Approximately one week later, patients were instructed

to begin range of motion exercises on a daily basis, gradually increasing activity until pre-operative range of motion was recovered (American Cancer Society, 1996). The main objective was to restore range of motion through patient self-care during the first two weeks after breast cancer surgery. Participating surgeons performed both traditional and breast-conserving surgery. All patients were discharged from the hospital within 48 hours with a drain that remained intact for at least three days after surgery.

The shift to short-stay breast cancer surgery moves post-surgical care from the tertiary health care setting into to the patient's home. The interdisciplinary health care team works together to avoid treatment delays between primary, secondary, and tertiary care. The APN is uniquely qualified to collaborate with physicians and nurses in order to identify and treat seroma formation, as well as to provide the patient education and referral process necessary to prevent serious sequella (Dontje, Sparks, & Given, 1996).

According to van Wersch, Bonnema, Prinsen, Pruyn, Wiggers, and van Geel (1997), a majority of breast cancer patients believed that they were poorly informed about how to receive help and guidance following discharge from the hospital, and wanted greater interaction between health care professionals. Continuity of care for breast cancer patients can be achieved when the APN, in collaboration with other health care providers, helps the patient meet her health care needs throughout the disease process.

The purpose of the secondary analysis was to determine whether a combination of possible risk factors identified in the literature predicted seroma formation. Individual variables were introduced simultaneously. Research questions for this secondary analysis include the following:

1) Does type of post-discharge care predict seroma formation?

2) Does type of surgery predict seroma formation?

3) Does patient Body Mass Index (BMI) predict seroma formation?

4) Does patient age predict seroma formation?

Seroma formation was defined as an accumulation of serous and/or lymphatic fluid in the surgical dead space resulting from the surgical removal of breast tissue and/or axillary lymph nodes that required follow-up treatment in the form of aspiration, lancing, or drain reinsertion. Type of post-discharge care was defined as (1) the parent study's post-discharge nursing intervention or (2) post-discharge care provided by a nursing agency, family members, friends, or the patient herself.

Participants in the intervention arm of the parent study received a two-week nursing protocol consisting of an average of three home visits and five phone calls designed to facilitate patient self-care and compliance with the post-discharge care plan. Some participants in the control arm received daily visits from a visiting nurse, usually over a one week period. Unlike the parent study's nursing intervention, visiting nurses focus a series of tasks, rather than enabling the patient to perform self-care. Women in the control arm received post-discharge care from a family member, friend or the patient herself. The hypothesis is that women receiving post-discharge care from a source other than the parent study's intervention nurse will be at greater risk for seroma formation.

The trend toward breast-conserving surgical methods is fairly recent, and its effect on seroma formation has not been widely studied. Seroma rates among women who had breast-conserving surgery, defined as lumpectomy with axillary node dissection, were

compared with the rate of seroma experienced by women who underwent traditional modified radical mastectomy or wide excision with axillary lymph node dissection. The hypothesis is that women who have traditional surgery are at greater risk for seroma formation, compared to women who undergo the less invasive breast-conserving surgery.

Two demographic variables, patient Body Mass Index (BMI) and age, also were considered in the secondary analysis as possible risk factors for seroma formation. BMI accounts for differences in body composition by defining the level of adiposity according to the relationship of weight to height. The hypothesis is that patients with high levels of adiposity (obesity) are at greater risk to develop a postoperative seroma than women with ideal or low BMI scores. Patient age was measured in years, with the hypothesis being that older women are at greater risk for seroma formation than younger women.

Review of the Literature

Risk of Seroma Formation Following Breast Cancer Surgery

Traditionally, definitive breast cancer surgery involved a two-stage diagnostic biopsy and therapeutic surgical procedure done on an inpatient basis, with hospital stays ranging from 23 hours to several days. However, recent surgical literature explores the effect of breast cancer surgery done on an outpatient basis, with the conclusion that it offers safe and cost-effective cancer management. The year 1991 was the first year that the total number of outpatient breast cancer surgical procedures surpassed the number of inpatient procedures in the United States (Goodman & Mendez, 1993).

In 1993, Goodman and Mendez conducted a retrospective review of 221 patients ranging in age from 34-87 years who, on an outpatient basis, underwent total mastectomy,

modified radical mastectomy, partial mastectomy with and without axillary node dissection, and axillary node dissection only. Drains were removed between 5 and 7 days postoperatively. The incidence of seromas requiring one or more aspirations was less than 15%, comparable with the incidence in patients operated on as inpatients.

Similarly, McManus, Topp, and Hopkins (1994) conducted a retrospective analysis of 118 patients ranging in age from 29 to 87 years, who, on an outpatient basis, underwent modified radical mastectomy, lumpectomy and axillary node dissection, and axillary node dissection alone. Patients who had undergone axillary dissection had their drains removed in 48 hours, while patients who had undergone mastectomy had their drains removed in 5-7 days. The study revealed that 87% (n = 90) of patients undergoing lumpectomy and axillary dissection did so in the outpatient setting, while 36% (n = 20) of modified radical mastectomy patients were treated on an outpatient basis. Although several seromas were managed by aspiration, only three patients required post-surgical hospitalization. The investigators concluded that same-day discharge was safe.

Post-surgical seroma remains a quandary because its etiology is unknown. Although seroma is generally defined as the accumulation of excess fluid in the surgical dead space, definitions in the literature vary. For example, Kumar, Lal, and Misra (1995) found a 28% incidence of seroma formation, defined as an accumulation of serous fluid underneath the mastectomy flap. Petrek, Peters, Cirrincione, and Thaler (1992), stratified subjects according to axillary dissection or modified radical mastectomy, and defined seroma as the accumulation of lymphatic fluid in the axillary space and accumulation of serum under the mastectomy flap. Holcombe, West, Mansel and Horgan (1995) found a

50-60% incidence of seroma requiring aspiration post axillary node dissection, but did not stipulate whether fluid was lymphatic or serous. In their study involving both traditional and breast-conserving surgical techniques, Burak, Goodman, Young, and Farrar (1997) found a 40% seroma rate overall, and concluded that seroma formation occurs as a consequence of both lymphatic disruption and oozing of capillary beds.

Sommers, Jablon, Kaplan, Sandler, and Rosenblatt (1991) defined seroma as a palpable collection of fluid in the axilla, and concluded that use of a closed suction drainage system after lumpectomy and axillary node dissection was advantageous in decreasing the degree of seroma formation. They randomized 227 patients scheduled for axillary node dissection into a drain group (108 cases) and a no drain group (119 cases). All drains were removed on the first postoperative day. Overall, 81.5% of patients developed postoperative seromas. In the drain group, 73.2% of patients required aspirations compared with 89.1% of patients in the no drain group. The mean number of aspirations in the drain group was 2.2, with a range of 0 to 11, and 3.3 in the no drain group, with a range of 0 to 11. These differences were found to be statistically significant ($p = 0.002$) using a two-sample t-test. Mean volume aspirated in the drain group was less than the no drain group (146.3 ml versus 266.1 ml, $p = 0.003$). Length of morbidity was 11.5 days in the drain group, statistically smaller than the no drain group ($p = 0.0002$).

Similarly, a study of 86 surgical patients by Holcombe, et al. (1995), found that frequency of postoperative seroma formation was significantly reduced for both mastectomy and breast conservation patients when drains were maintained for a longer duration of time [7 cases (18%) versus 16 cases (35%), $P < 0.001$; X^2]. Dietrick-Gallagher

and Hyzinski (1989) also found some evidence that seroma frequency is negatively correlated to the amount of time drains are maintained. Their study compared randomly assigned groups of patients who were discharged from the hospital before drain removal (n = 15), and after drain removal (n = 22). While a t-test revealed no statistically significant differences in complication rates between the groups, the rate of seroma development was higher in the hospitalized partial mastectomy group. The investigators speculate that this finding may be related to the fact that hospitalized patients had drainage systems intact for an average of only 3.72 days, compared with 6.25 days for the early discharge group.

In contrast, Yii, Murphy, and Orr (1995), conducted a trial with 100 consecutive patients undergoing modified radical mastectomy or breast conserving surgery, and concluded that seroma formation is not significantly associated with the amount of time the drain remained intact for either type of surgery. Seroma was defined as fluid accumulation in the surgical site requiring aspiration. Factors considered in this study included drainage volume within a 48 hour period, total drainage volume, and amount of time closed suction drains remained intact between two randomly assigned groups of patients. One group had drains removed four days after surgery, and the other group had drains removed 48 hours after surgery. Seromas developed in three cases (6%) in the group with drains in place for four days, compared to 5 cases (10%) among the group with drains in place for 48 hours, a finding that does not represent a significant difference between the two groups. The investigators concluded that drains may be removed on the second postoperative day without increased risk of seroma formation.

Similarly, a study of 98 modified radical mastectomy patients by Parikh, et al. (1992), suggests that seroma formation, defined as an accumulation of fluid in the surgical site that required aspiration, is not associated with the amount of time drains are maintained after surgery. Patients were randomized into one of two groups: one group had early drain removal (on the third postoperative day), while the second group had late drain removal (on the sixth postoperative day). Neither mean volumes of seromas aspirated ($p = 0.799$) nor in the number of aspirations ($p = 0.740$) were statistically different between groups, and the investigators concluded that drains may be removed by the third postoperative day. The one factor shown to influence seroma volumes was body weight greater than 65 kilograms. Height was not included as a factor.

Type of Post-Discharge Care

The literature is limited regarding the effect of post-discharge nursing protocol on seroma formation among short-stay breast cancer patients. Over the past decade, health care delivery in the United States has changed dramatically, and the results of those changes can now be analyzed. Outcome measures such as seroma formation provide a yardstick by which to evaluate the effects of economic and organizational change in the health care system on the breast cancer patient. Thus, the impetus for this study.

In 1989 at the Hospital of the University of Pennsylvania in Philadelphia, Dietrick-Gallagher and Hyzinski implemented an early discharge education protocol for 15 mastectomy patients that included pre-discharge nursing instruction about incision and drain care, a discharge instruction sheet, and a postoperative office visit. Rate of seroma formation among the early discharge group was then compared with the rate of seroma

among 22 randomly selected mastectomy patients who remained hospitalized until the drain was removed. The groups were similar in age, had the same number of lymph nodes removed, and had similar numbers of positive lymph nodes. A t-test was used to analyze the data, and no significant difference in seroma formation was found between groups. Among the early discharge group, the rate of seroma formation was 29%, compared to 30% among hospitalized patients.

Holcombe, et al. (1995) also compared hospital nursing care with home nursing care in a pilot study at the University of Wales College of Medicine, Cardiff, United Kingdom. One hundred and one women who had a modified radical mastectomy or wide excision and axillary lymph node dissection as part of their breast cancer treatment were studied. The mean age was 59 years within a range of 29-76 years. Thirty-nine patients opted for early discharge, which was, on average, five days shorter than the control group. The early discharge plan was explained during preoperative counseling, and included an instruction and an information sheet about care of the drain. Investigators found that patients in the intervention group had lower rates of seroma formation when compared to patients who received more days of hospital care (18% vs 34%, $p = 0.001$; X^2). Both studies comment on the fact that patients who recovered at home tended to keep drains intact for a longer time period than women who recovered in the hospital.

In a study of 208 breast cancer patients from his practice at Henry Ford Hospital in Detroit, Michigan, Kambouris (1995) found that approximately 45% of participants were treated with modified radical mastectomy, 35% with breast-conserving surgery, and the remaining with a variety of procedures tailored to specific circumstances. All

participants underwent complete axillary node dissection on an outpatient basis (hospital stays of 24 hours or less) and were permitted unrestricted use of arm and shoulder after surgery. Thirty-two percent of the participants developed a seroma; however, the study design did not include a control group for comparison.

All three of the studies above emphasized the cost savings when length of hospital stays are reduced. The majority of patients in each study underwent traditional modified radical mastectomy. Seroma incidence varied between 18% and 32% for patients who opted for short-stay surgery, while patients who had a longer hospital stays were found to have seroma rates between 30% and 34%.

Type of Surgery

The literature suggests that seroma formation is common after all types of breast cancer surgery (Yii, Murphy & Orr, 1995; Holcombe et al., 1995; Kumar, et al., 1995); however, the risk of seroma formation among patients who opt for breast conserving surgery as opposed to modified radical mastectomy or wide excision is unclear. In the late 1980's and early 1990's, several prospective, randomized trials demonstrated that survival after lumpectomy, axillary dissection, and radiotherapy was equivalent to survival after mastectomy (Morrow & Hassett, 1994; Fisher, Redmond, & Poisson, 1989; Veronesi, Banfi, & Del Vecchio, 1986). As a consequence, breast conserving surgery has become the therapy of choice, unless specifically contraindicated. However, few studies take into account the impact of the surgical method on seroma formation.

In 1985, Tejler and Aspergren conducted a study involving 385 patients to compare complications after modified radical mastectomy (324 cases or 82%) and breast

conserving surgery, defined as segmental resection with axillary dissection (71 cases or 18%). They found seromas in 36.5% of wounds after modified radical mastectomy, and in 26.8% after segmental resection. In addition, seroma formation was positively correlated with increasing age ($p \leq 0.05$).

More recently, Burak, Goodman, Young, and Farrar (1997), conducted a prospective, randomized study of 101 patients who underwent modified radical mastectomy or breast conserving surgery, defined as lumpectomy with axillary node dissection. The mean age was 54 (range 31-86 years), average weight was 68.9 kg (range 40-140 kg), and the average Quitelet Obesity Index was 26.5 (range 17-54). Using stepwise logistic regression, findings indicated that breast-conserving surgery ($p = 0.001$), increased patient age ($p = 0.016$), increased patient weight ($p = 0.122$), and high amounts of initial 72-hour wound drainage ($p = 0.001$) were risk factors for seroma formation.

Patient BMI and Age

Many researchers have considered the impact of demographic variables, most often patient weight and age, on seroma formation. In the literature, patient weight is usually defined as number of pounds or kilograms. As mentioned earlier, Parikh, et al. (1992), found a positive correlation between patient weight and seroma formation. Similarly, Kumar, et al., (1995) reported a positive correlation between seroma formation and both weight and age in a prospective study involving a convenience sample of 64 female patients undergoing modified radical mastectomy. Patients who developed postoperative seroma were designated as group A (n=18, or 28%) and patients who did not develop seroma were designated as group B (n=46, or 72%). Group A patients were

significantly older ($p = 0.02$) and heavier ($p \leq 0.05$). However, the investigators note that a significantly greater number of group A patients were hypertensive, and that the age and weight factors should be viewed as factors influencing the cardiovascular status of the patients rather than being determinants of seroma formation.

As mentioned earlier, Burak, et al., (1997), suggest that obesity and increasing age put women at risk for seroma formation. In 1985, Tejler and Aspegrem followed 313 modified radical mastectomy patients and found 116 seromas (37.1%). The occurrence of seroma was positively correlated with increasing age. However, a retrospective analysis of 351 modified radical mastectomy patients by Chilson, Chan, and Lonser (1992) found no association between patient age and seroma.

Summary and Critique of the Literature Review

Review of the literature reveals contradictory findings, which indicates that seroma formation has a non-linear relationship with factors such as age, weight, and type of surgery. For the most part, research was conducted by surgeons who, in response to the rising cost of hospitalization, were trying to identify risk factors for seroma formation in hopes of reducing the number of days patients remained in the hospital after surgery. Statistical techniques that test the association between variables, such as t-tests and chi-square, were most often used. Several studies were based on very small sample sizes, which diminished the veracity of their conclusions and contributed to the contradictory findings evident in the literature overall.

Surgical practice varies slightly, but there is general consensus that a closed-suction drainage system maintained for two to seven days after surgery is standard

practice (Dietrick-Gallagher & Hyzinski, 1989; Holcombe, et al., 1995; Parikh et al., 1992; Sommers et al., 1991; Yii, et al., 1995). Studies questioning the effect of treatment variables, such as type of surgery and post-discharge care, are sparse, despite the widespread adoption of breast-conserving surgery and shorter hospital stays.

The impact of nursing care on seroma formation is seldom addressed in the literature, and is often limited to comparisons of hospital nursing care versus home nursing care. Studies looking at the impact of demographic variables such as patient age and weight on seroma formation also have been poorly defined and have yielded contradictory findings. Therefore, the APN will benefit from further study of these variables in order to identify possible risk factors for seroma formation, and to improve patient self-care following breast cancer surgery.

Discussion and Rationale for Proposed Study

The secondary analysis of *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) utilized logistic regression to analyze the impact of four independent variables - type of post-discharge care, type of surgery, patient BMI, and patient age - as a collection of factors that, in and of themselves, may not be significant, but in relation to the other variables may be found to have significant predictive value in regard to seroma formation. Variables found to predict seroma formation were then considered within the context of patient education and continuity of care for patients with breast cancer who are recovering from surgery at home.

In response to recent changes in the surgical treatment of breast cancer patients, the secondary analysis examined the frequency of seroma formation among women who

had breast conserving surgery, defined as lumpectomy with axillary node dissection, compared to women who had a modified radical mastectomy or wide excision with axillary node dissection, in order to indicate whether risk of seroma formation is associated with the type of surgical procedure experienced by the patient.

The weight variable was considered in the more explicit terms of Body Mass Index (BMI). This index accounts for differences in body composition by defining the level of adiposity according to the relationship of weight to height, and has the least correlation with body height and the highest correlation with independent measures of adiposity for adults, including the elderly. BMI is defined according to the following scoring method: (A) under 20 is associated with underweight and may be associated with health problems for some individuals; (B) 20-25 is the "ideal" range associated with the lowest risk of illness for most people; (C) 25-27 is associated with overweight and may be associated with health problems for some people; (D) 29 or greater for women indicates obesity (Wardlaw & Insel, 1993).

Patient age has long been suspect as a variable associated with seroma formation. For the secondary analysis, age was measured in years as a continuous variable.

Short hospital stays following breast cancer surgery is a fairly recent phenomenon, and its impact on recovery could be substantial. Patients recovering at home require much more instruction about post-discharge care and the risk of potential surgical complications. As post-surgical care moves out of the hospital and into the patient's home, the APN is uniquely qualified to collaborate with tertiary health care providers in order to ensure continuity of care for the patient with a diagnosis of breast cancer.

Conceptual Framework

Dorothea Orem's Theory of Self-Care

In today's health care delivery system, women are usually discharged from the hospital within 48 hours after breast cancer surgery, and are more reliant on self and family for post-surgical care that was previously provided by hospital nurses (Clark & Kent, 1997; Kambouris, 1996). This secondary analysis seeks information about possible risk factors associated with seroma formation, and about how that information can be employed by the APN on an interdisciplinary health care team planning post-discharge care. Dorothea Orem's self-care emphasis can be used by the APN to ensure minimal provider intrusion with maximum patient responsiveness.

Dorothea Orem's conceptual model of nursing focuses on individuals' self-care needs and their capabilities for meeting those needs. According to Orem, the goal of nursing is to help people meet their needs at the therapeutic level and on a continual basis (Orem, 1995). People are considered legitimately in need of nursing care when a self-care deficit is diagnosed by the nurse. Orem's major theoretical concepts are: (1) conditioning factors; (2) health deviation; (3) self-care requisite; (4) self-care; (5) therapeutic self-care demand; (6) self-care deficit; (7) nursing agency; and (8) self-care agency (see Figure 1).

This secondary analysis attempted to identify possible risk factors for seroma formation, as a way for the APN to facilitate self-care. As a consequence, Orem's first three concepts - conditioning factors, health deviation, and self-care requisites - are considered relevant to this study (see Figure 2).

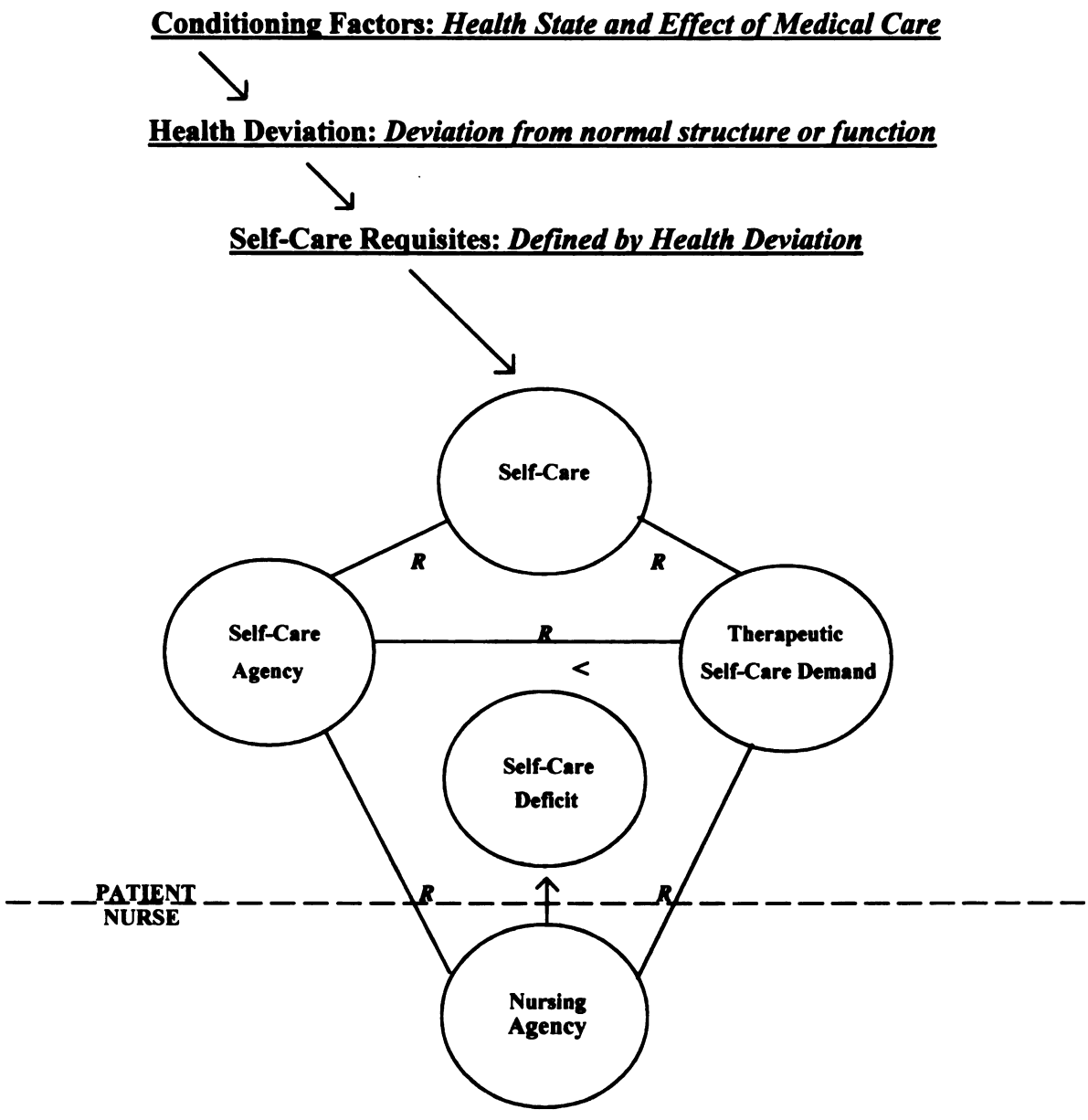

Figure 1. Dorothea Orem's conceptual framework for nursing (R = relationship;< = deficit relationship, current or projected), Orem (1995).

Conditioning Factors

Orem defines conditioning factors as the patient's health state, the effects of medical care, and environmental conditions that predispose the patient to a particular health deviation. In this secondary analysis, conditioning factors are the four risk factors

under study. Two factors, namely type of post discharge care and type of surgery, involve the effects of medical care on seroma formation. The last two factors - patient BMI and age - consider the effects of the patient's health state on seroma formation (see Figure 2).

Health Deviation

A health deviation is an illness or other aberration from the normal structural and functional integrity of the patient. The health deviation determines what kind of self-care requirements must be met by the patient. In the secondary analysis, seroma formation is the health deviation under consideration (see Figure2).

Self-Care Requisites

Orem identifies three types of self-care requisites: (1) universal self-care requisites that involve activities such as adequate intake of air, water, and nutrition in the maintenance of the human structure and its functioning; (2) developmental self-care requisites that involve successful passage through various stages in the life cycle; and (3) health-deviation self-care requisites that involve the actions that must be performed by the patient in response to a particular medical treatment modality. In this secondary analysis, the self-care requisite is defined by the health deviation (seroma formation) as prevention of serious sequella related to seroma formation (see Figure 2).

Conceptual Definition of Seroma

A seroma was defined in this study as an accumulation of serous and/or lymphatic fluid in the surgical dead space that required treatment in the form of aspiration, lancing, or reinsertion of a drain. Within the context of Orem's theory, seroma formation is

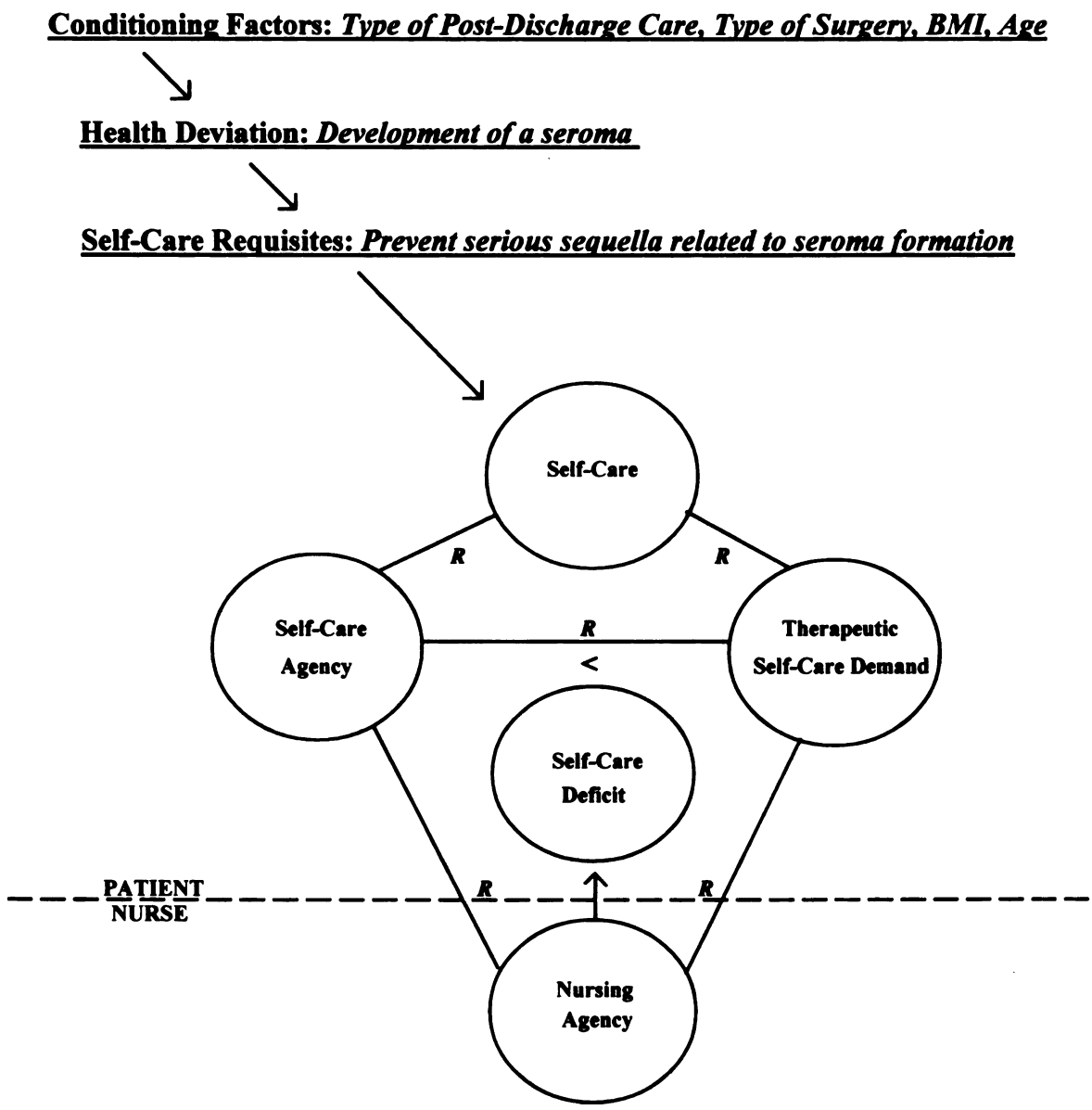

Figure 2. Adapted from Dorothea Orem's conceptual framework for nursing (R = relationship; < = deficit relationship, current or projected).

defined as a health deviation that mandates particular self-care requisites, namely, prevention of serious sequella related to seroma formation.

Conceptual Definition of Type of Post-Discharge Care

For the secondary analysis, post-discharge care was defined as either the parent study's nursing intervention or conventional care provided by a nursing agency, friends,

family, or the patient herself. According to Orem's model, type of post-discharge care is defined as a conditioning factor that results from the effects of medical care.

Conceptual Definition of Type of Surgery

In the secondary analysis, type of surgery was limited to breast conservation, defined as lumpectomy with axillary node dissection, and traditional surgery, defined as modified radical mastectomy (removal of breast and axillary lymph nodes) and simple mastectomy (removal of breast only). Under Orem's model, type of surgery is categorized as a conditioning factor related to the effect of medical care.

Conceptual Definition of BMI and Age

BMI was defined as a combination of the patient's height and weight, as outlined in Section 2. In Orem's model, patient BMI was categorized as a conditioning factor related to the patient's health state. Age in years was calculated for adult women in the study, and also was defined as a conditioning factor related to the patient's health state.

Methods

Sample

This study is a secondary analysis of 102 participants from the federal grant, *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325), Gwen Wyatt, RN, PhD, Principle Investigator. The convenience sample was drawn from women with known carcinoma of the breast residing and receiving surgical care in the State of Michigan. Eligibility criteria for participants in the parent study were: (1) age 21 or older, (2) confirmed diagnosis of breast cancer, (3) surgical treatment that included placement of a closed-suction drain, and (4) current residence within 40 miles of

the surgeon's office. Exclusionary criteria were: (1) pregnancy, (2) active psychiatric disorder, (3) primary language other than English, (4) postoperative hospital stay longer than 48 hours, (5) residence in a nursing home or assisted living facility, (6) in situ breast tumors, and (7) reconstructive surgery concurrent with removal of cancerous tissue.

All participants underwent lumpectomy with axillary lymph node dissection, modified radical mastectomy with axillary lymph node dissection, wide excision with axillary lymph node dissection, or simple mastectomy without axillary lymph node dissection. Patients stayed in the hospital 48 hours or less after surgery and returned home with a closed suction drain.

Parent Study Design

The parent study, *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325), followed an experimental design and assigned participants to one of two arms: (1) the intervention arm, in which participants received a nursing protocol that emphasized self-care; and (2) the control arm, which included patients receiving conventional care from a community nursing agency, care by a friend or family member, or self-care. Participants were randomly assigned to either the intervention arm or the control arm of the study. Women assigned to the intervention arm received a self-care nursing protocol from the parent study for a two-week period immediately after surgery. The control group received conventional post-discharge care in the home for a one-week period from a community home nursing agency, or care was provided by a friend, family member, or the patient herself. Random assignment was carried out in groups of ten to ensure equal distribution of subjects at any point in time.

In the parent study, breast cancer surgery was defined as: (1) lumpectomy with axillary lymph node dissection; (2) modified radical mastectomy; (3) wide excision with lymph node dissection; and (4) simple mastectomy without lymph node dissection. Study recruiters obtained written consent from patients in Lansing, Charlotte, Pontiac, and Troy Michigan. Participants were randomly assigned to an intervention group, who received the study's nursing care in the home for a two week period after surgery, or a control group, who received nursing care in the home by various home health agencies, by family members, or by the patient herself. Four weeks after surgery, participants were interviewed about their recovery. The goal of the study was to determine the optimal amount and type of home nursing care needed after short hospital stays.

The nursing protocol administered to women in the intervention arm of the parent study focuses on self-care. Study nurses instructed patients to engage only in light activities of daily living while the drain was intact, and to maintain their drains until total 24-hour drainage was under 20-30 ml for three consecutive days. After the drain was removed, participants were taught range of motion exercises (American Cancer Society, 1996) and encouraged to perform them daily, gradually increasing the number of repetitions until preoperative range of motion was restored. The protocol was designed to facilitate patient self-care by providing instruction and information about incision and drain care, the risk of postoperative complications, and the disease process.

Secondary Analysis: Design

Secondary analysis involves the use of data gathered in a previous study to test new hypotheses or explore new relationships (Polit & Hungler, 1995). It is an efficient

and economical design because it analyzes data that the parent study has already collected, but did not examine in primary research questions. The use of available data makes it possible to bypass time-consuming and costly steps in the research process.

Secondary analysis of *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) examines possible risk factors associated with seroma formation, and considers the implications for the APN on an inter-disciplinary health care team planning post-discharge care. The dependent variable, seroma, was linked to four antecedent independent variables: (1) type of post-discharge care, (2) type of surgery, (3) patient Body Mass Index (BMI), and (4) patient age.

The secondary analysis asks whether type of post-discharge care predicts seroma formation. The two arms of the parent study were used to define the independent variable. The hypothesis is that patients receiving conventional care by a visiting nurse, family, friends, or the patient herself, are at greater risk for seroma formation compared to women participating in the parent study's nursing intervention. The second hypothesis is that women undergoing traditional breast cancer surgery are at greater risk for seroma formation than those receiving breast-conserving surgery. The third hypothesis posits that obesity, as defined by the Body Mass Index, is a risk factor for seroma formation, and the fourth hypothesis is that elder patients are at greater risk for seroma formation.

The major disadvantage of secondary analysis is that the data set might be deficient or problematic in one or more ways, such as the sample used or the variables measured (Polit & Hungler, 1995). However, the parent study's sample - a convenience sample of 102 women with a confirmed diagnosis of breast cancer undergoing short-stay

surgery - provided a relatively large, random sample of women that represented the population at risk for seroma formation. Moreover, the parent study defined seroma formation in the same way as the secondary analysis. Due to its experimental design, the parent study provided a way to distinguish types of post-discharge care following breast cancer surgery by offering a comparison between the parent study's post-discharge nursing intervention with conventional care, which included agency home care nursing, care provided by friends or family, or by the patient herself (self-care).

Other variables in the secondary analysis, such as type of surgery, patient BMI, and patient age, were easily obtained by combining existing variables from the parent study. For example, patient BMI (BMI = weight in kilograms divided by height in meters squared) was computed by converting patient height and weight into meters and kilograms, and applying the appropriate formula. Patient age in years was derived by subtracting patient birth date from surgery date. Type of surgery was reduced to two categories by recoding modified radical mastectomy and wide excision with axillary lymph node dissection as traditional surgery, and lumpectomy with axillary lymph node dissection as breast-conserving surgery.

From an original sample of 115 subjects, 13 women who had a mastectomy without axillary lymph node dissection were excluded from the secondary analysis. Women who did not have axillary lymph node dissection did not experience significant lymphatic disruption, and therefore were not representative of the majority of breast cancer patients. As a consequence, the secondary analysis is based on a sample of 102 women from the parent study.

Procedures

A retrospective chart audit of 102 breast cancer patients participating in *A Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) was performed by a registered nurse on the research staff four months after breast cancer surgery. These data were entered into the CI-3 interview database, and were reformatted for secondary analysis in the SPSS 7.5 database.

Protection of Human Subjects

Approval from the University Committee on Research Involving Human Subjects (UCRIHS) was obtained (see Appendix A). Secondary analysis falls under the 1-E exempt category, which is defined as research involving the collection or study of existing data, if the source is recorded by the investigator in such a manner that subjects cannot be identified. There were no physical, psychological, social, legal or economic risks associated with the secondary analysis. Data were blinded to maintain each participant's anonymity.

Operational Definitions of the Variables

The dependent variable, seroma formation, was coded as present or absent. Absent was coded (0) and present was coded (1). Independent variables were defined as follows: Type of post-discharge care was coded as: (0) conventional care provided by local home care agency nurses, family caregivers, friends, or the patient herself (control arm), or (1) nursing care received by subjects in the intervention arm of the parent study. Type of surgery was coded as: (0) breast-conserving surgery consisting of lumpectomy with axillary node dissection; or (1) traditional surgery, which included modified radical

mastectomy with axillary node dissection or wide excision with axillary node dissection. BMI was coded as a continuous two-digit number ranging from 18 to 83, and was calculated by the formula resulting in weight in kilograms divided by height in meters squared. Age was coded as a continuous three-digit number expressed as years ranging from 021 to 100.

Data Management

Data was coded and entered into the SPSS 7.5 database for statistical analysis. Frequency distributions and measures of central tendency were calculated for all variables of interest. Data from the parent study was cleaned of all outliers and missing data. Review of the literature shows that statistical techniques that test the association between variables, such as t-tests and chi-square, were most often used. This secondary analysis used logistic regression to consider the four independent variables as a collection of factors that, in and of themselves, may be significant, but in relation to the other variables could be found to have significant predictive value in regard to seroma formation.

Surgery has been established as an important factor in understanding seroma formation. Studies of seroma formation have contained multiple risk factors which may contribute to a better knowledge of how to predict the odds of developing a seroma when particular risk factors are present. Since multiple risk factors may be involved, several risk factors must be controlled for simultaneously in the analysis of variables associated with seroma formation. Logistic regression uses maximum likelihood estimation to analyze the relationship between multiple independent variables and a dependent variable that is categorical. The types of regression problems for which logistic regression models

apply are characterized by the dependent variable being dichotomous or binary. In the secondary analysis, the dependent variable is binary in the form of 1 or 0, present/absent.

The strength of logistic regression is that it requires far fewer assumptions about the population in which the data originated. Nevertheless, it may produce misleading results if findings are basically unstable, inconsistent, or idiosyncratic to a particular sample. It maximizes chance associations in a data set and often produces findings that vary substantially across samples, especially in studies using many predictor variables and a small sample (Downs, 1988).

Randomization of the study subjects was successful with no differences found between the intervention and control arms. Thorndike's (1978) rule of thumb for a rough estimate of the minimal sample size for multivariate analysis is 10 subjects per variable plus 50 additional subjects. Secondary analysis of *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) met that criteria - it examined four independent variables and had data from 102 subjects. The large sample in the secondary analysis (n=102), allowed for a more accurate assessment of the coefficient estimate of the independent variables.

Logistic regression requires interval variables, that is, variables that can be measured with numeric precision (Lewis-Beck, 1980). Non-interval variables can be considered as dichotomies. In the secondary analysis, the dependent variable was a dichotomy - seroma: present/absent. Two of the independent variables also were dichotomous: (1) type of post-discharge care: intervention/control; and (2) type of surgery: breast conserving/traditional. Patient BMI and age were interval variables.

The equation was: $Log\ p/1 - p = b_0 + b_1$ *(type of post-discharge care)* $+ b_2$ *(type of surgery)* $+ b_3$ *(BMI)* $+ b_4$ *(age in years)* $+ e$. Significance of p was set at 0.05. The hypothesis was that the risk for seroma formation increases with (1) conventional post-discharge care (received by the parent study's control arm), (2) traditional breast surgery, (3) increasing BMI score, and (4) increasing patient age. Individual variables were introduced simultaneously, beta coefficients were calculated, and the statistical significance of each coefficient was determined.

Results

Demographics

Participants included women age 21 or older admitted for short-stay surgery (48 hours or less) as first treatment for breast cancer. One hundred and two women were studied. Body Mass Index ranged from 18 to 83, with a mean of 30.45. Ages ranged from 33 to 84 years, with a mean of 57 years.

Of 102 women, 29 (28.4%) developed a seroma. A total of 78 (76.4%) women elected to have breast conserving surgery, and 24 women (23.6%) had a traditional modified radical mastectomy or wide excision with axillary lymph node dissection. There was no statistically significant difference in demographics between the intervention and control arms of the parent study (see Table 1).

Demographics in Table 2 are taken from the parent study and are based on n = 100. Overall, 93% of participants were Caucasian, and 64% had at least some college education. All participants spoke and read English, and all had received some level of formal education. The majority of participants (58%) were employed before surgery.

TABLE 1

Frequency of Type of Surgery and Seroma Formation (n = 102)

	Intervention (n=51)		Control (n=51)		Total (n=102)	
	n	%	n	%	n	%
Type of Surgery						
Breast Conserving	41	80.4%	37	71.5%	78	76.4%
Traditional	10	19.6%	14	28.5%	24	23.6%
Post-Surgical Complications						
Seroma Formation	14	27.5%	15	29.4%	29	28.4%

Married women also comprised the majority (57%), compared to participants who were divorced, single, or widowed (see Table 2).

Answers to Research Questions

Multiple regression is a technique used to predict a single dependent variable using a number of independent variables. However, when the dependent variable is dichotomous, as in the case of seroma formation (present/absent), a logistic function is used to simulate a normal distribution. The maximum likelihood model selects the beta coefficients that make the observed results of the dependent variable most likely, and eliminates all independent variables that are not statistically significant and therefore poor predictors of the dependent variable (seroma formation).

A subset of independent variables that were considered potential predictors of the dependent variable would make the observed rates of the dependent variable most "likely". As mentioned previously, the equation representing these variables is as follows:

$Log\ p/1 - p = b_0 + b_1$ *(type of post-*discharge care) + b_2 (type of surgery) + b_3 (BMI) + b_4

TABLE 2

Demographics (n = 100)

	Intervention (n=51)		Control (n=49)		Total (n=100)	
	n	%	n	%	n	%
Ethnicity						
Caucasian	48	94.1%	45	91.8%	93	93.0%
Other	3	5.9%	4	8.2%	7	7.0%
Marital Status						
Married	28	54.9%	29	59.2%	57	57.0%
Divorced/Separated	11	21.6%	7	14.3%	18	18.0%
Never Married	8	15.7%	3	6.1%	11	11.0%
Widowed	4	7.8%	10	20.4%	14	14.0%
Employment Status						
Employed before surgery	26	51.0%	32	65.3%	58	58.0%
Not employed before surgery	25	49.0%	17	34.7%	42	42.0%
Education						
Completed graduate degree	8	15.7%	12	24.5%	20	20.0%
Completed college	9	17.6%	6	12.2%	15	15.0%
Completed some college	16	31.4%	17	34.7%	33	33.0%
Completed high school	11	21.6%	9	18.4%	20	20.0%
Completed some high school	5	9.8%	3	6.1%	8	8.0%
Completed grade school	2	3.9%	2	4.1%	4	4.0%
No formal education	0	0.0%	0	0.0%	0	0.0%

(age in years) + *e*, where *p* = probability of seroma formation. The initial model for predicting seroma formation included type of surgery, type of post-discharge care, BMI, and age. Both BMI ($p = 0.7925$) and age ($p = 0.2769$) were found to be non-significant in predicting seroma formation and were eliminated from the model. Type of post-discharge care was kept in the model regardless of its ability to predict seroma formation, as it was an inherent part of the parent study design (see Table 3).

TABLE 3

Main Effect Model (n = 102)

Variable	B	SE B	*p*
Type of Surgery	1.6575	0.5002	0.0008*
Type of Post-Discharge Care	0.0922	0.4732	0.8454

*$p \leq 0.001$

To assess the magnitude of the relationship of type of surgery, type of post-discharge care, BMI, and age to seroma formation, change in the maximum likelihood was determined (see Table 4). In this case, -2 times the log of the likelihood (-2LL) was used, since the likelihood is a small number (less than one). A good model is one that results in a high likelihood of the observed results, which translates to a small value for -2LL. For example, if a model fits perfectly, the likelihood is 1, and -2 times the log likelihood is 0.

The initial model includes the constant beta coefficient only ($Log\ p/1 - p = b_0 + e$). It is considered the baseline model, and had a -2LL of 121.111 This model was used for comparison with the Full Model, which included all beta coefficients [b_1 *(type of post-discharge care),* b_2 *(type of surgery),* b_3 *(BMI),* and b_4 *(age in years)*]. The -2LL decreased to 108.552. The model chi-square, 12.56 ($p = 0.014$), is the difference between the initial model and the Full Model. Thus, the model chi-square tests the null hypothesis, namely, that the beta coefficients for all of the terms in the current model, except the constant, are 0. The degrees of freedom for the model chi-square are the difference between the number of variables in the two models. The Full Model was found to be statistically

TABLE 4

Testing for Confounding Variables (n = 102)

	-2LL	Change in -2LL	*p*
Baseline Model	121.111	----	----
b_0	----	----	----
Full Model	108.552	12.559	0.0140
b_1 Type of Post-Discharge Care	----	----	0.8426
b_2 Type of Surgery	----	----	0.0013
b_3 BMI	----	----	0.7925
b_4 Age	----	----	0.2769
Main Effect Model	110.198	1.678	0.0014*
b_1 Type of Post-Discharge Care	----	----	0.8426
b_2 Type of Surgery	----	----	0.0013

*$p \leq 0.01$

significant ($p = 0.0014$), therefore, it was necessary to determine which of the variables was contributing to the success of the model.

Of the four independent variables - type of post-discharge care (defined as the parent study's intervention or control group), type of surgery (traditional or breast-conserving), BMI and age (in years) - only type of surgery was found to be statistically significant ($p = 0.0013$), indicating that type of surgery is a possible predictor of seroma formation. None of the other variables in and of themselves contribute as a main effect variable, and therefore are not considered to be predictors of seroma formation. As mentioned earlier, type of post-discharge care must also remain in the model, not because

it was a main effect variable, but because it was the basis upon which the parent study sample was randomized.

Type of surgery was identified as the main effect variable. However, the other variables - type of post-discharge care, BMI and age - could be possible confounders or effect modifiers on the main effect variable. To test for confounding effects, the question becomes: Is there an increased risk of seroma formation for those recovering from traditional surgery versus breast-conserving surgery, after adjusting for (1) type of post-discharge care, (2) BMI, and (3) age. The baseline model now becomes the Main Effect Model: type of surgery and type of post-discharge care, [b_1 *(type of post-discharge care),* b_2 *(type of surgery)]* with a -2LL of 110.198.

To check for confounding effects of BMI and age on the Main Effect Model (the new baseline model), a comparison was made between the -2LL of the full model [b_1 *(type of post-discharge care)* + b_2 *(type of surgery)*+ b_4 *(age in years)*], and the -2LL of the Main Effect Model. The change in -2LL of the main effect was less than 20%[X^2_2 = 1.678 ($p \geq 0.05$)], which is not statistically significant. Therefore, age and BMI do not confound the relationship between surgery and seroma formation.

In addition, the beta coefficient of surgery in the baseline model was 1.6732. With the addition of BMI and age, the beta coefficient decreased to 1.6515. This comparison presents with only a 0.9% change [$p(b_3$ *(BMI)* = 0.6746, and $p(b_4$ *(age)* = 0.6546)]. Therefore, neither BMI nor age confound the effect of surgery on seroma.

The final step in analyzing the Main Effect Model was to evaluate whether type of post-discharge care was an effect modifier on type of surgery and seroma. In other words,

was the relationship between seroma formation and surgery type different for differing types of post-discharge care? With $p = 0.8426$, post-discharge care was not found to be a statistically significant effect modifier (see Table 4).

The -2LL for type of post-discharge care (110.236) and type of surgery (110.198) were then compared, revealing a non-significant difference of 0.038. This finding indicated that type of post-discharge care does not confound the predictive effect that surgery has on seroma formation.

The odds ratio for the main effect variable - type of surgery - was 5.3292 ($p = .0008$), which suggests that the risk of seroma formation may be over five times greater for women receiving traditional surgery compared to women undergoing breast-conserving surgery. This finding supports the hypothesis that women having traditional surgery are at greater risk for seroma formation than women who opt for breast-conserving surgery.

The Full Model included the remaining independent variables - patient BMI and age - in order to assess whether or not these variables confounded the results of the Main Effect Model. Log Likelihood (-2LL) results were compared between the two models to determine if the new variables confounded the relationship between surgery and seroma formation. Comparison of beta coefficients revealed a change of 0.9% between the Full Model and the Main Effect Model, which indicates that neither BMI nor age confound the effect of surgery on seroma formation.

Effect modification was used to test whether the relationship between seroma formation and surgery type was modified by the combination of type of surgery and BMI .

If BMI was an effect modifier, then the relationship between seroma formation and surgery type would be different for different levels of age and BMI. Results revealed p = 0.6746, and suggested that the combination of age and surgery had no effect on the relationship between surgery and seroma formation. Similarly, the modifying effect of type of surgery and age showed that p = 0.6546. Again, the conclusion is that the combination of BMI and type of surgery did not significantly modify the relationship between surgery and seroma formation.

Discussion

Interpretation of the Findings

The hypothesis that there is an increased risk of seroma formation with (1) post-discharge care received by the parent study's control arm, (2) patient BMI and (3) patient age was not substantiated. The only hypothesis found to predict seroma formation was related to type of surgery. Results of the logistic regression indicate that women having traditional surgical procedures that involve the removal of large amounts of breast tissue may have a five times greater risk of developing a postoperative seroma compared to women undergoing breast-conserving surgery.

Variables such as patient age and weight have been found to be associated with seroma formation in previous studies that utilized parametric tests with large samples, and non-parametric tests when sample sizes were small. This secondary analysis attempted to reproduce those findings with a more powerful statistical method - logistic regression. However, considering the contradictory findings represented in the literature, it is not surprising that the demographic variables failed to predict seroma formation

under more rigorous testing. Nevertheless, the impact of demographic variables may be misrepresented in this secondary analysis, given that 76.4% of the participants elected to have breast conserving surgery, compared to only 23.6% who had mastectomy or wide excision with axillary lymph node dissection. It is possible that these factors do have an impact on seroma formation for women undergoing traditional surgery, as previous studies have suggested, but were not detectable in this study because of the small sampling of women having traditional surgery. Perhaps a study with equal group size would yield different results.

Results of the secondary analysis suggest that type of post-discharge care does not influence the risk of postoperative seroma formation. Given the fact that the etiology of seroma formation remains unknown, the preventive effects of post-discharge nursing care cannot be determined. Therefore, the focus of post-discharge nursing should be on preventing the serious sequella of seroma formation through patient education, early detection, and prompt treatment.

In terms of type of surgery and its effect on seroma formation, the recent shift to less invasive, short-stay surgery has left the literature wanting. Few studies compare traditional surgical techniques with breast-conserving surgery. Nevertheless, results of this secondary analysis suggest that breast-conserving techniques may result in significantly fewer postoperative seromas than traditional breast surgery.

Discussion of Results with the Conceptual Model

With regard to Orem's conceptual model, the results of this secondary analysis indicate that self-care may commence before surgery, when the patient begins to consider

surgical options. Breast-conserving surgery is relatively new, and the consequences of this technique are not well known. Advanced Practice Nurses who provide patient education before surgery can incorporate the findings about increased risk of seroma formation with traditional surgery into their teaching about the consequences of surgical intervention, which may help women decide among surgical treatment options.

The secondary analysis indicated that the type of post-discharge care women received after breast cancer surgery had no effect on the incidence of seroma. As a consequence, Orem's model of self-care cannot be fully applied to the problem of seroma formation. Orem's focus is on learned, goal-oriented actions performed by the patient or the nurse in order to meet therapeutic demands defined by a particular health deviation. Since the secondary analysis indicated that the type of post-discharge care did not have an effect on seroma formation, no new information was revealed to suggest that particular actions taken by the APN prevent seroma formation. Thus, the aim of self-care after surgery is early detection of seroma formation, and prompt medical treatment in order to prevent infection, sepsis, and delayed wound healing.

Implications for the Advanced Practice Nurse

In an attempt to reduce health care costs, surgical management of breast cancer patients now consists of hospital stays of 24 hours or less, and patients are increasingly expected to provide their own care during the recovery period at home. The APN is uniquely qualified to design patient education that emphasizes self-care, and to provide supervision of post-discharge progress in the home. In order to provide continuity of care and to ensure positive post-surgical outcomes for breast cancer patients, utilization of the

entire interdisciplinary health team may be the most effective approach to achieving comprehensive patient care.

For the APN, Orem's model provides a practical framework from which to plan pre and post-discharge education for the breast cancer patient. In light of the findings of the secondary analysis, pre-surgical education should include information about the various surgical options, including traditional and breast-conserving methods, and the effects of a particular surgical method on seroma formation. After surgery, patient education should include information about the likelihood and consequences of seroma formation, the signs and symptoms of seroma, and a plan to seek prompt medical treatment if seroma formation occurs.

Case management of the breast cancer patient is increasingly important as time spent in the tertiary health care setting decreases. Outcome goals which include the prevention of serious sequella of seroma formation need to be clearly identified, discussed with the patient, and carefully monitored in order to ensure patient progress and to improve standards of care.

Recommendations for Further Research

Much remains to be learned about the etiology of seroma formation. Although the prevalence of seroma is considerable, its prevention is not yet feasible. Consequently, more attention should be paid to preventing negative outcomes of seroma. Nursing studies that document how prompt recognition and treatment of seroma reduce serious complications, such as infection and delays in wound healing, could be used to improve post-discharge planning and lower health care costs.

Results of this secondary analysis indicate that seroma formation affects 28.4% of post-surgical breast cancer patients. Variables not considered in the secondary analysis, such as medical comorbidities and immune system characteristics, may shed light on the cause of seroma formation. Therefore, continued research into the etiology and management of seroma formation is needed to improve post-surgical outcomes for breast cancer patients.

Summary

Secondary analysis of 102 participants from *A Subacute Care Nursing Intervention for Short-Stay Breast Cancer Surgery* (DAMD17-96-1-6325) suggests that seroma formation affects a large number of women following breast cancer surgery. Based on the unequal group size of this analysis, patients undergoing traditional surgery (modified radical mastectomy or wide excision with axillary lymph node dissection) may have a five-times greater risk of seroma formation, compared to patients opting for breast-conserving surgery, regardless of the type of post-discharge care they received, or personal characteristics such as BMI and age.

The etiology of seroma formation is unknown, and its prevention remains problematic. Before surgery, the APN on the interdisciplinary health team should instruct patients on making the best surgical decision for their set of circumstances. After surgery, the APN can help prevent the serious sequella of seroma formation by teaching the patient how to recognize the signs and symptoms of seroma formation, and by developing a plan to seek prompt medical treatment if seroma formation occurs.

APPENDIX

APPENDIX A

The University Committee on Research Involving Human Subjects IRB# 99154

MICHIGAN STATE
UNIVERSITY

March 12, 1999

TO: Dr. Gwen WYATT
A230 Life Sciences
College Of Nursing

RE: IRB# **99154** CATEGORY: 1-E

APPROVAL DATE: March 9, 1999

TITLE: POSTOPERATIVE SEROMA FORMATION FOLLOWING BREAST CANCER SURGERY: IMPLICATIONS FOR THE ADVANCED PRACTICE NURSE

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

RENEWALS: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Projects continuing beyond one year must be renewed with the green renewal form. A maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for a complete review.

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

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

If we can be of further assistance, please contact us at 517 355-2180 or via email: UCRIHS@pilot.msu.edu. Please note that all UCRIHS forms are located on the web: http://www.msu.edu/unit/vprgs/UCRIHS/

Sincerely,

David E. Wright, Ph. D.
UCRIHS Chair

DEW: bd

cc: Mary Bloomfield

OFFICE OF
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