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FOREWORD

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Rebecca A. Sullivan 8/24/98
PI - Signature Date

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5. INTRODUCTION

Nature of the Problem

Little is known about what constitutes appropriate care for older women with breast cancer (1) because until recently, women ≥ 70 years of age were excluded from most clinical trials. It is perhaps not surprising, therefore, that there is considerable variation in how older women are treated (2-9). There are several reasons why careful longitudinal observational studies involving older women with breast cancer need to be performed. First, because of spiraling health care costs, Congress and third party payers are demanding that we determine, insofar as possible, what constitutes effective care for our patients. Although randomized clinical trials will continue to be the gold standard for assessing treatment efficacy, large numbers of older women are not likely to be enrolled in such clinical trials and those that are enrolled will not be representative of those cared for by most practicing physicians (1). Second, the variations in diagnostic evaluation and initial treatment that have been observed may or may not matter in terms of important short and long-term clinical outcomes (recurrence and mortality) and in terms of psychosocial outcomes (physical, social, and emotional function). Evidence linking variations in care received by older patients and variations in clinical and psychosocial outcomes is sparse. For example, only very recently has the first study been published which links nondefinitive therapy with an increased risk of mortality (10). In addition there are limited data regarding psychosocial outcomes. However, there is evidence to suggest that more extensive surgery is a risk factor for poor upper body function among older women, but not for poor emotional function (11). Because of the chronic nature of early stage breast cancer, what happens in terms of follow-up care (adjuvant therapy and surveillance testing) may have a greater effect on patients' well-being than initial treatment. Third, because the incidence of breast cancer is continuing to rise, because the incidence increases with age (12), appearing only to level off at about age 80-85 (13), and because the numbers of women 65 years of age are rapidly increasing, the absolute number of new breast cancer cases will continue to grow into the foreseeable future, as will the proportion of cases involving older women.

Background/Previous Studies

The current study is designed to identify determinants of variations in adjuvant hormonal/chemotherapy and follow-up care among older women with early stage breast cancer and the effects of these variations on health-related quality of life and breast cancer-specific function.

Adjuvant Tamoxifen Therapy has both Benefits and Risks/Barriers

Benefits. Adjuvant tamoxifen therapy has been shown to decrease both rates of recurrence and mortality in older women with early stage breast cancer. A meta-analysis of clinical trials worldwide that included 2656 women ≥ 70 years of age, documented decreases in both recurrence (28%) and overall mortality (21%) rates among patients with node-positive disease treated with tamoxifen. Similar proportional risk reductions were found for node-negative patients, although the absolute risk reduction was greater for women who were node-positive. In addition, the magnitude of risk reduction, both with respect to recurrence and mortality, was

similar across three postmenopausal age groups: 50-59, 60-69, and 70+. Adjuvant tamoxifen therapy also was beneficial for women with hormone receptor-poor tumors, albeit to a lesser extent than in those with hormone receptor-rich tumors. Treatment with tamoxifen also prevents the development of contralateral breast cancer (14). There are non-breast cancer benefits of therapy for postmenopausal women as well. Tamoxifen may prevent osteoporosis (15) and lower cholesterol levels (16). Recent reports from Europe suggest that tamoxifen reduces the risk of hospitalization for cardiovascular disease and for fatal myocardial infarction (17-18).

Risks/Barriers to Treatment. Tamoxifen is prescribed as the result of a definite disease (breast cancer) in order to reduce the probability of events in the future: breast cancer recurrence; the development of contralateral breast cancer; death; and possibly, cardiovascular and osteoporotic complications. Although there are proven health benefits, the risks and costs are not insignificant. First, although some Medigap policies include a prescription medication benefit, many do not; most older persons must pay out-of-pocket for their medications, many of which cost a dollar or more per day (e.g., 19, 20). Generic tamoxifen, at the recommended dose of 20 mg/day, will cost most patients \$85/month or more over a two to five year period. Second, taking tamoxifen may make patients feel worse, not better. One clinical trial involving younger postmenopausal women documented about a 4% dropout rate due to side effects, including nausea, hot flashes, edema, and vaginitis (21). Another clinical trial, also involving women < 65 years of age, documented persistent vasomotor, gynecological, or other major side effects in 48% of tamoxifen treated women compared with 21% of controls. Moderate to severe hot flashes, for example, persisted for 12 months in 22% of tamoxifen subjects vs. 5% of controls (22). In a clinical trial of women 65 - 84 years of age, Cummings and colleagues noted that 42% of women taking tamoxifen experienced mild toxicity symptoms by Eastern Cooperative Oncology Group criteria (mild, moderate, and severe), 21% experienced moderate symptoms, and 3% experienced severe symptoms (23). Third, treatment with tamoxifen increases the risk of rare, but serious illnesses. Deep vein thrombosis can complicate the use of tamoxifen and this risk appears to be greater in women ≥ 65 years (24). In addition, recent studies from Europe and the United States are relatively consistent in demonstrating an increased risk of endometrial cancer among tamoxifen users (25, 26). About 75% of endometrial cancers occur in women ≥ 60 years of age, and this already elevated base rate appears to be more than doubled by the addition of tamoxifen treatment (26). In light of the growing body of information about the risk of endometrial cancer, annual gynecological examinations, ranging from a history and physical examination to pelvic and/or endovaginal ultrasound and/or endometrial sampling are recommended for patients receiving tamoxifen (26). However, there is uncertainty as to the best approach to surveillance (27-29).

Evidence for Adjuvant Chemotherapy Treatment Efficacy

The value of adjuvant chemotherapy with or without tamoxifen in postmenopausal women is controversial, and in women over 70 years of age, has not been well-studied. In the meta-analysis described above, adjuvant chemotherapy resulted in only a 10% reduction in the mortality of women aged 60-69, although recurrences were reduced significantly. There were only 274 women enrolled in chemotherapy trials who were ≥ 70 years of age, and in these, adjuvant chemotherapy did not appear beneficial (14). Clearly adjuvant chemotherapy cannot be considered standard treatment for postmenopausal women, especially those ≥ 70 years of age. It is possible, however, that adjuvant chemotherapy may be of benefit to subgroups of patients,

especially those with aggressive disease. Because so little is known about the use of chemotherapy in older persons, the current project is addressing the following descriptive questions: 1) What proportion of older women, both with stage I and stage II breast cancer, currently receive adjuvant chemotherapy? and 2) What patient and physician characteristics are associated with the receipt of chemotherapy?

Surveillance for Recurrence following Initial Therapy

Although women are routinely followed by clinical examination and laboratory testing for evidence of recurrence, there is no evidence that this strategy results in earlier detection of recurrence or reduces mortality (30). Furthermore, case series evaluating the yield of various screening strategies have documented that most recurrences are detected either by patients themselves or by clinical examination (31-35). Only about 15% of recurrences are detected by surveillance testing which, in 1990 dollars amounts to an annual cost of about \$1200/patient. No published studies have examined the costs and benefits, in human terms (either increasing anxiety or allaying fears), of surveillance testing, although a clinical trial evaluating these issues is reported to be in progress (35). Furthermore, none of the published studies have involved older women. Information about surveillance testing in older women is conspicuously lacking, including the types and frequency of testing and its impact on patient outcomes, particularly psychosocial outcomes. The current study is addressing the following questions: 1) How often are patients being seen and by which physicians during the early years following primary treatment? and 2) What are the types and frequency of surveillance tests and what are the effects of this testing on patient outcomes?

Summary: Given the national mandate to determine what constitutes effective health care and the fact that breast cancer is a disease primarily of older women (nearly half of newly diagnosed cases of breast cancer occur in women ≥ 65 years of age), we are conducting a longitudinal study of newly diagnosed older women with stage I and II disease: 1) to identify variations in follow-up care, and 2) to link these variations to patient outcomes. In conjunction with limited clinical trial data, this will be valuable information to assist clinicians in medical decision-making. Together, these two types of data will be able to inform the development of guidelines for the care of older women with breast cancer.

Purpose of the Current Study

As described above, we are filling important gaps in knowledge by addressing the following **study questions** in our current study:

1. What patient and provider characteristics are associated with the receipt of hormonal and/or chemotherapy?
2. What are the effects of hormonal treatment on patients' quality of life?
3. What patient and provider characteristics are associated with the receipt of surveillance tests?
4. What are the effects of surveillance testing on patients' quality of life?

Our specific aims are:

1. To describe patterns of adjuvant hormonal and chemotherapy in older women, and factors associated with receipt of these therapies.
2. To characterize and quantify the breast cancer-related care received by older women during the early years following diagnosis.
3. To determine the effects of ongoing breast cancer care (adjuvant therapy and disease surveillance) on patients' quality of life.

Overview of Methods of Approach

As described in more detail below (**6. BODY**), we are studying a cohort of women ≥ 55 years of age with newly diagnosed early stage breast cancer over a 2-5 year time period. Initial telephone interviews are conducted at 3-5 months following initial definitive treatment, with subsequent interviews occurring approximately two years later, and annually thereafter. Medical records are abstracted, beginning at the time of diagnosis and continuing until project completion, or the development of metastatic disease or subject death. The medical record review covering the initial treatment period and the baseline interview were funded by the National Cancer Institute. The follow-up interviews and medical record reviews are funded under the current project by the US Army Medical Research, Development, Acquisition and Logistics Command.

6. BODY

Overview and Findings from the Parent Study Funded by the National Cancer Institute (CA57754)

Funding from the National Cancer Institute (NCI) enabled us to enroll the cohort that is being followed longitudinally for the current project. Patients ≥ 55 years of age with newly diagnosed early stage breast cancer, being cared for at one of five hospitals with academic affiliation in Boston, Massachusetts, were enrolled between January 1993 and April 1996. Eligible patients were sent an introductory letter signed by their surgeon and a consent form approximately three months following initial surgical treatment. This was followed by a telephone call from our interviewer who further explained the study, answered questions, and obtained informed consent. Data were collected via a review of patients' surgical records, and a 30 minute computer-assisted telephone interview with consenting eligible patients. Data collected from medical records included: histology, stage, estrogen receptor status, surgery performed, additional therapies received, and medical comorbidities. Our patient telephone interview included questions about: general health-related quality of life, breast cancer-specific quality of life, medical comorbidities, the treatment decision-making process, treatment priorities, perceptions of doctor-patient communication, and demographic characteristics.

We have published two papers in *Cancer* that summarize the methods findings from the baseline data. They are included in the Appendix. The first paper reports factors associated with the receipt of primary tumor therapy:

THE IMPACT OF AGE, MARITAL STATUS, AND PHYSICIAN-PATIENT INTERACTIONS ON THE CARE OF OLDER WOMEN WITH BREAST CANCER (see Appendix for complete published report)

Abstract

Background: Understanding why older women with breast cancer do not receive definitive treatment is critical if we are to reduce disparities in mortality between younger and older women.

Methods: We studied 302 women ≥ 55 years of age with early stage breast cancer. Data were collected from surgical records and telephone interviews with the women. The main outcome was receipt of definitive primary tumor therapy, defined as either modified radical mastectomy or breast conserving surgery with axillary dissection followed by radiation therapy.

Results: The majority (56%) of women underwent breast conserving surgery and axillary dissection followed by radiation therapy. After statistical control for comorbidity, physical function, tumor size, and node status, patients' age, marital status, and the number of times breast cancer specialists discussed treatment options were significantly associated with the receipt of definitive primary tumor therapy.

Conclusions: In the setting of newly diagnosed breast cancer in older women where there is clinical uncertainty as to the most appropriate therapies, patients may be better served by being offered choices among definitive therapies. In discussing therapies with them, physicians must be sensitive to their fears and concerns about the monetary costs and functional consequences of treatment in relation to expected benefits.

The second paper reports factors associated with general and breast cancer specific emotional health:

BREAST CANCER CARE IN OLDER WOMEN: SOURCES OF INFORMATION, SOCIAL SUPPORT, AND EMOTIONAL HEALTH OUTCOMES (see Appendix for complete published report)

Abstract

Background. We studied older women with breast cancer and asked: 1) Where do older women get information about breast cancer care and how helpful do they perceive each of these sources to be? 2) What aspects of social support are associated with older women's general and breast cancer-specific emotional health outcomes?

Methods. To be eligible, women had to be at least 55 years of age and newly diagnosed with stage I or II breast cancer. Data were collected from women's surgical records and a 35 minute computer-assisted telephone interview.

Results. Almost all women rated information that was provided by their breast cancer physicians as *very* or *somewhat helpful*. Written materials provided by breast cancer physicians were also frequently rated as *very* or *somewhat helpful*. Women's marital status; their religious service attendance; their ratings of their physicians' technical and interpersonal care; and their

perceptions of their own abilities to communicate with their physicians were significantly associated with both general and breast cancer-specific emotional health outcomes (all $p < 0.05$). Conclusions. Although older women obtain information about breast cancer from a variety of sources, they rely heavily on their physicians for information. Identifying older women with breast cancer at risk for poor emotional health outcomes and developing methods to enhance physician-patient communication in this setting may improve these outcomes.

Two related manuscripts, but whose topics were not central to the specific aims of the original grant, have also been submitted for publication. The first addresses upper-body function following primary tumor therapy:

RISK FACTORS FOR A DECLINE IN UPPER BODY FUNCTION FOLLOWING TREATMENT FOR EARLY STAGE BREAST CANCER (see Appendix for complete manuscript)

Abstract

Purpose: To identify risk factors for a decline in upper body function following treatment for early stage breast cancer.

Methods: We conducted a cross-sectional observational study of 215 women ≥ 55 years of age newly diagnosed with early stage breast cancer interviewed three to five months following their definitive surgery. Patients were classified as having impaired upper body function related to their breast cancer treatment if: 1) they reported having no difficulty in performing any of three tasks requiring upper body function (pushing or pulling large objects; lifting objects weighing more than 10 pounds; and reaching or extending arms above shoulder level) prior to treatment, but reported that any of these tasks were *somewhat* or *very* difficult in the four weeks prior to interview, or 2) they reported that performing any of the three tasks requiring upper body function was *somewhat* difficult prior to treatment, but reported that any of these tasks were *very* difficult in the four weeks prior to interview.

Results: In multiple logistic regression models, both the extent and type of primary tumor therapy and cardiopulmonary comorbidity were significantly associated with a decline in upper body function following breast cancer treatment.

Conclusion: Given the critical importance of upper body function in maintaining independent living, clinicians should consider the functional consequences of treatment when they discuss treatment options and post-operative care with older women who have early stage breast cancer.

The second is a methodological paper that compares different strategies for measuring comorbidity.

COMPARISON OF INTERVIEW-BASED AND MEDICAL RECORD-BASED INDICES OF COMORBIDITY AMONG BREAST CANCER PATIENTS (see Appendix for complete manuscript)

Abstract

Objectives: To compare patient interview-based and medical record-based measures of comorbidity and their relation to a range of patient outcomes, including primary tumor therapy and mortality, self-reported upper body function, and overall physical function.

Methods: 303 breast cancer patients age 55 years or older and diagnosed at 1 of 5 Boston hospitals were enrolled. Patient interviews and medical record abstracts provided the information necessary to construct the Charlson index, Satariano index, and a new interview-based index of cardiopulmonary comorbidity. These indices were used alone and in combination to predict the patient outcomes.

Results: The indices of comorbidity corresponded well with one another. The record-based Charlson index was the only index that predicted receipt of definitive therapy. No index of comorbidity predicted mortality over the short follow-up period. The new interview-based index of cardiopulmonary comorbidity was a better predictor of upper-body function and overall physical function than the interview-based or medical record-based Charlson or Satariano indices of comorbidity.

Conclusion: Older breast cancer patients are able to provide information about their diseases and related symptoms that correlates well with medical record-based measures of comorbidity and displays similar patterns of predictive power. A new self-reported measure of cardiopulmonary comorbidity performs better than the medical record-based measures for predicting patient-related functional outcomes.

Experimental Methods Used for Current Study

Institutional Review Board Approval: All annual Institutional Review Board approvals were obtained from each of the study sites. We received approval from Faulkner Hospital on November 14, 1995; from Boston Medical Center on November 15, 1995; from Boston City Hospital on December 27, 1995; from Beth Israel Hospital on October 16, 1995; and from New England Medical Center on December 12, 1995. Approvals are updated annually.

Study Implementation

Subject Enrollment and First Follow-up Interview in the Current Study. Subjects enrolled in the NCI study were mailed a consent packet 20 months after their diagnosis date. This time interval was chosen because it was the shortest interval from initial diagnosis possible with the initiation of the US Army Research, Development, Acquisition and Logistics Command funding.

It should be noted that the sample size available for study and the sample characteristics were constrained by the design and implementation of the parent NCI study. Specifically, although enrollment for the parent study was extended until April 1996, we did not achieve the sample size of 350 that we had originally planned (the reasons for this were detailed in the 1997 report). In addition, the original study was designed to compare younger postmenopausal women with older postmenopausal women. Two factors resulted in the youngest group of women (55-64 years of age) being the greatest contributors to our sample, and the oldest group of women (75+) being the smallest contributor. First, the number of women 55-64 years of age at risk for breast cancer is far greater than the number of women 75+ years of age at risk. Second, we, like all other investigators, experienced the highest refusal rate among the oldest group of women.

We have completed data collection for the first follow-up interview. Of the 303 subjects who were eligible, 250 (83%) participated in this first follow-up interview. The reasons for non-participation include: 1) inability to contact – 30 (10%), 2) refusal – 16 (5%), 3) death – 5 (2%), and 4) too ill – 2 (1%).

Second Follow-up Interview. Our second follow-up interview occurs approximately 12 months after the first follow-up interview. To date, 217 subjects have completed their second follow-up interview. A total of 41 (16%) have not participated. Eighteen could not be reached because residence and telephone numbers had changed. Eleven patients had died (4%) and two were too ill to participate. Ten (4%) refused to participate. As of this writing, 19 interviews for the second follow-up are yet to be completed. Note that we attempt to locate and interview subjects who participated in the baseline interview but who could not be located for the first follow-up interview.

Third Follow-up Interview. Our third follow-up interview occurs approximately 12 months after the second follow-up interview. To date, 144 subjects have completed their third and final follow-up interview. A total of 30 (17%) have not participated. Seventeen could not be reached because residence and telephone numbers had changes. Eight had died (5%) and two were too ill to participate. Three (2 %) refused to participate. As of this writing, 83 interviews for the third follow-up are yet to be completed.

Collection of Surveillance Data. Medical record abstractions began in November 1994, and additional medical record abstractions are performed annually for each participant. To assess inter-rater reliability, a 20% random sample of charts are reviewed by Dr. Silliman. Medical record abstractions have been completed for subjects who have completed the first follow-up interview. We were able complete 247 of 250 abstractions (99%). Two records were inaccessible because the patients had died and one patient received no further treatment or care. Abstractions have been completed for 174 of the 217 (80%) of subjects who have completed the second follow-up interview; and 89 of the 144 subjects (62%) who have completed the third follow-up interview.

Results for Current Study

Study Question #1. What patient and provider characteristics are associated with the receipt of hormonal and/or chemotherapy?

Based on reviewers' comments about our manuscript addressing primary tumor therapy ("The Impact of Age, Marital Status, and Physician-Patient Interactions on the Care of Older Women with Breast Cancer" – see Appendix), we chose to address this question by analyzing the outcome according to the receipt of both primary tumor therapy as well as adjuvant systemic therapy. Thus, patients could be classified as yes/yes, yes/no, no/yes, and no/no. The manuscript describing our findings has been submitted for publication (see Appendix):

QUALITY OF CARE FOR OLDER WOMEN WITH BREAST CANCER: IS SURGEON GENDER IMPORTANT? (see Appendix for complete manuscript)

Abstract

Context. - Over the past decade and a half a substantial literature has documented age-related variations in breast cancer care. Accumulating evidence suggests that these variations impact the

health outcomes (breast cancer recurrence and mortality) of older women with breast cancer. Surgeon gender may be an important source of age-related variations in care.

Objective. - To examine the relationship between surgeon gender and primary tumor therapy and systemic adjuvant therapy among 303 older women with early stage breast cancer cared for by 21 surgeons in Boston, Massachusetts.

Design. - Cross-sectional observational study.

Patients. - Women at least 55 years of age with newly diagnosed stage I or II breast cancer.

Main Outcome Measure. - Definitive primary tumor therapy and systemic adjuvant therapy.

Results. - Controlling for age and stage, patients of female surgeons were less likely to receive non-definitive treatment, with the strongest effect being observed for the receipt of neither definitive primary tumor therapy nor systemic adjuvant therapy (OR 0.24; 95% CI 0.1, 0.4).

Conclusion. - Women with early stage breast cancer cared for by female surgeons are more likely to receive standard therapies. Understanding the reasons for this could inform the design of effective interventions to improve the quality of breast cancer care for older women.

Study Question #2. What are the effects of hormonal treatment on patients' quality of life?

Study Question #4. What are the effects of surveillance testing on patients' quality of life?

Systemic Adjuvant Therapy. Sixty-seven percent of patients (n=168) reported that their physicians had recommended adjuvant tamoxifen therapy and 93% (n=157) of these women reported that they had actually begun tamoxifen therapy. Of the 157 patients who had taken tamoxifen at any time, 86 (55%) reported that they had experienced side effects. Table 1 shows the type of side effects experienced by the women. The most common side effect reported was hot flashes, which were experienced by 74% of the women. Vaginitis and depression were two other side effects reported by an important minority of patients. Nonetheless, at the time of the interview, 140 patients (89%) reported that they were still taking tamoxifen.

Only 44 (18%) patients reported that adjuvant chemotherapy was recommended, and all but one of these patients received treatment. Most (40 of 43) patients who began chemotherapy reported that they experienced side effects. Tables 2 shows the type of side effects experienced by these patients. The two most commonly reported side effects, each reported by over 90% of the women, were hair loss and fatigue; 83% of women reported that they were troubled by nausea. However, only four patients did not complete a complete course of therapy.

Surveillance Care. During the first surveillance period (between 6 and 18 months following diagnosis), subjects were seen up to seven times each by surgeons, radiation oncologists, and medical oncologists. Among those that had at least one visit, the average number of visits during this year was 2.2 for surgeons, 1.24 for radiation oncologists, and 1.24 for medical oncologists. During that year they had up to five mammograms (15% had none; the average was 1.68), up to six carcinoembryonic antigen (CEA) tests (65% had none; the average was 0.77), and up to seven complete blood counts (53% had none; the average was 1.0) and liver function tests (56% had none; the average was 1.0).

Approximately 60% of women reported that they felt calm before their breast cancer-related visits, while 27% reported that they did not. Similarly, 19% of women reported that they felt upset before their visit, while 71% stated that they did not. The vast majority of women reported that they felt good after a visit with their breast cancer specialist. Only 3% of women stated that they felt scared after a visit; 95% reported that they felt confident. Patients were

asked how they felt they were doing with worries and feelings surrounding their cancer. Most women, almost two years beyond their breast care diagnosis, reported that they feel they are doing well managing long-term life concerns. More than half of the patients (59%) felt they were doing excellent or very good with dealing with feelings of anger, fear and grief. Similarly, over half of the patients felt they were doing excellent or very good with their worries regarding their family's ability to manage if they got sicker, or worries about who would take care of them if they got sicker (54% and 49% respectively). However, approximately 16% of patients did not feel they were doing well with worries about recurrence of cancer. Indeed, during this first follow-up period, thirteen women developed recurrences, eleven of which were local and two of which were to bone. Most (n=8) were identified by physical examination, with mammography and bone scan being diagnostic in two instances each.

Quality of Life Outcomes. As described above (p. 9-10), we have identified factors associated with both general and breast cancer specific emotional health (two important and relevant measures of breast cancer patients' quality of life) at baseline. Using these same measures as outcomes, we have recently completed multivariate analyses relating adjuvant chemo and hormonal therapy to general and breast cancer specific emotional health at the time of the first follow-up interview (about 20 months after diagnosis). Candidate variables for our multivariate models included: baseline measures of the relevant outcome, age, stage, comorbidity, primary tumor therapy, systemic adjuvant therapy, surgeon gender, and number and type of visits (surgeon, radiation oncologist, and medical oncologist) during the first year of follow-up care. With change in general emotional health from baseline to follow-up as the dependent variable, the independent variables ($p < 0.05$) retained in the final model were surgeon gender, baseline emotional health, and the interaction term containing surgeon gender and baseline emotional health. Women who at baseline had the lowest emotional health scores had greater improvement if they were cared for by female surgeons than those cared for by male surgeons. With change in breast cancer specific emotional health from baseline to follow-up as the dependent variable, the independent variables ($p < 0.05$) retained in the final model were surgeon gender and baseline breast cancer specific emotional health. On average, patients of female surgeons scored five points higher on our breast cancer specific emotional health scale over the follow-up period, compared to those of male surgeons. In addition, those who initially scored low on the breast cancer specific emotional health scale improved by 10 points, whereas those who started out high declined about 16 points. Note that neither the type of treatment nor the number or types of medical care visits were retained in these models. Rather, surgeon gender had an important enduring effect on longer-term outcomes, consistent with what we have found with respect to short-term outcomes (see p. 9-10 and Appendix).

Study Question #3. What patient and provider characteristics are associated with the receipt of surveillance tests?

Our analyses thus far have focussed on the number of cancer specialist physician visits visits made during the first year of surveillance care. Factors associated on bivariate analysis with number of cancer specialist visits include: age, marital status, and systemic adjuvant therapy (all $p < 0.05$). The relationship between stage and number of visits was of borderline significance ($p=0.08$). Of interest, patients with stage I disease were more likely to have more visits than patients with stage II disease. On multivariate logistic regression analysis, younger

patients, those with stage I disease, and those receiving hormonal therapy were more likely to have more total visits to cancer specialists than older patients, those with stage II disease, or those who received chemotherapy or no adjuvant systemic therapy (all $p < 0.05$).

Additional Analyses:

Second Follow-Up Interview.

Our second follow-up interview occurs approximately 12 months after the first interview and includes much of the same information as the first follow-up interview. In addition, it asks more specific questions about adjuvant tamoxifen therapy and gynecological surveillance and evaluation. We added these latter questions because of the concern about endometrial cancer risk and the uncertainty regarding the value of screening in this setting. To date, 217 subjects have completed their second follow-up interview.

Adjuvant tamoxifen therapy and gynecological care. Sixty-five percent ($n=140$) reported that they had been prescribed tamoxifen. Of the current tamoxifen users ($n=115$, 82%), 47% reported experiencing side effects. The most common side effects were hot flashes (61%), vaginitis (17%), and depression (11%). In addition, 29 patients complained of 19 other side effects that they attributed to tamoxifen. Seventeen of the 25 women (68%) who had stopped taking tamoxifen did so because of side effects.

We asked patients who had ever taken tamoxifen if they were referred to a gynecologist. Of the 135 who responded, 25% had been referred to a gynecologist once they had started taking tamoxifen. For patients who received gynecological care, 11% had had a vaginal ultrasound, and 7% had had an endometrial biopsy.

Emotional Adjustment. Patients were asked how they felt they were doing with worries and feelings about their breast cancer. More than half of the patients (57%) felt they were doing excellent or very good with dealing with feelings of anger, fear and grief. Similarly, over half of the patients felt they were doing excellent or very good with their worries regarding their family's ability to manage if they got sicker, or worries about who would take care of them if they got sicker (56% and 51% respectively). However, approximately 18% of patients did not feel they were doing well with worries about recurrence of cancer. Nonetheless, after asking patients to respond to certain statements about how they were feeling about their lives, 80% responded they "enjoyed life", 89% had "accepted their illness", and 71% were "content with their quality of life". Of note, 26% of patients were concerned about the risk of cancer in their family members.

Third Follow-up Interview.

Our third follow-up interview is a subset of questions from the second follow-up interview. Questions that no longer pertain to patients three years after their primary treatment have been dropped, and in addition we will be asking more in depth questions about long term side-effects from surgery and radiation therapy. A total of 144 women have completed their third and final interview.

Long-term side-effects. By the time of the third interview (approximately 44 months after diagnosis), 15% reported that it was somewhat or very difficult to push or pull large objects, 17% reported difficulty extending their arms over their head, and 26% reported that it was difficult to lift items over 10 pounds. In addition, 19% reported persistent swelling or other difficulties with the arm on the side of their surgery and 28% reported persistent numbness or pain in the axilla.

Mortality. As of this writing, twenty-four subjects have died (8%). We have obtained death certificates for 20 of these. Thirteen (65%) died of breast cancer and 7 (35%) died of other causes.

Plans for the 05 Project Year.

We have been granted a two year extension of the project so that we can obtain complete follow-up for all consenting subjects. During the 05 Project Year we will complete Follow-up 2 interviews and medical record surveillance abstractions for the comparable time period. We will also complete Follow-up 3 interviews and medical record reviews as they become due.

Note that medical abstracting ends if patients develop metastatic disease or die. If patients develop in-breast recurrence or contralateral disease, abstracting is suspended until the second episode of definitive treatment has been completed. For each subject, medical record abstracting continues until the four year anniversary date of her initial treatment. To date, medical record abstracting has been completed on 89 subjects. For patients who have died, we will continue to obtain copies of death certificates from the Massachusetts Department of Health to determine the immediate and underlying causes of death.

7. CONCLUSIONS

Because the current project is as yet not complete, we cannot comment regarding project implications. However, it is important to note that several products have emanated thus far from the combination of the parent study and the current study.

1) Dr. Silliman (Principal Investigator) and colleagues submitted a grant proposal to the National Cancer Institute June 1, 1995 entitled "Adjuvant Tamoxifen Therapy in Old Age: Determinants and Consequences" (R01 CA/AG 70818). It was funded and began September 30, 1996. The current project is much smaller in scope but provided important preliminary data for the new project. This new project is examining patterns of adjuvant tamoxifen prescribing patterns in much more detail and is enrolling patients ≥ 65 years of age at four sites (Los Angeles, Minnesota, Rhode Island, and North Carolina). Almost 400 women have consented to participate thus far and the target enrollment figure is 800. About half are ≥ 75 years of age.

2) Dr. Silliman was invited to speak at the Cancer in the Elderly 1996 Conference (November 1996), at a lecture series sponsored by the Massachusetts Department of Health (January 1997), and at a special meeting of medical oncology educators in Puerto Rico (February 1997).

3) Dr. Silliman was invited to participate in a two and one-half day retreat to assist the National Cancer Institute's Breast Cancer Progress Review Group (September 1997) in developing a breast cancer research agenda for the next five years.

4) Dr. Silliman was invited to write an editorial as a companion to an article on age-related treatment variations published in the Journal of the National Cancer Institute June 4, 1996.

5) Two manuscripts have been published:

a. Silliman RA, Troyan SL, Guadagnoli E, Kaplan SH, Greenfield S. The impact of age, marital status, and physician-patient interactions on the care of older women with breast cancer. *Cancer* 1997; 80:1326-34.

b. Silliman RA, Dukes KA, Sullivan LM, Kaplan SH. Breast cancer care in older women: Sources of information, social support, and emotional health outcomes. *Cancer* 1998; 81:706-11.

6) Three additional manuscripts have been submitted:

Silliman RA, Prout MN, Field T, Kalish SC, Colton T. Risk factors for a decline in upper body function following therapy for early stage breast cancer.

Silliman RA, Demissie S, Troyan SL. Quality of care for older women with breast cancer: Is surgeon gender important?

Silliman RA, Lash TL. Comparison of interview-based and medical record-based indices of comorbidity among breast cancer patients.

7) Dr. Silliman has co-authored three book chapters with Dr. Lodovico Balducci:

a. Balducci L, Silliman RA, Baekey P. Breast cancer: An oncological perspective - Part I. In: Balducci L, Lyman GH, Ershler WB, eds. *Comprehensive Geriatric Oncology*. Australia:Harwood Academic Publishers, 1998:629-660.

b. Silliman RA, Balducci L. Breast cancer: A geriatric perspective - Part II. In: Balducci L, Lyman GH, Ershler WB, eds. *Comprehensive Geriatric Oncology*. Australia:Harwood Academic Publishers, 1998:661-664.

c. Silliman RA, Balducci L. Breast cancer. In: Gallo J, Busby-Whitehead J, Rabins P, Silliman R, Murphy J, eds. *Reichel's Care of the Elderly: Clinical Aspects of Aging* (5th ed). Baltimore: Williams & Wilkins, in press.

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Table 1. Reported Side Effects of Tamoxifen Treatment (n=86)	
Type of Side Effect	n (%)
Hot flashes	64 (74)
Vaginitis	21 (24)
Depression	18 (21)
Nausea	8 (9)
Phlebitis	2 (2)
Edema	2 (2)
Other	34 (40)

Table 2. Reported Side Effects of Chemotherapy (n=40)	
Type of Side Effect	n (%)
Hair loss	37 (93)
Fatigue	37 (95)
Nausea	33 (83)
Depression	22 (55)
Flu Symptoms	17 (43)
Mouth Sores	13 (33)
Other	12 (30)

Appendix

The Impact of Age, Marital Status, and Physician-Patient Interactions on the Care of Older Women with Breast Carcinoma

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Understanding why older women with breast carcinoma do not receive definitive treatment is critical if disparities in mortality between younger and older women are to be reduced. With this in mind, the authors studied 302 women age ≥ 55 years with early stage breast carcinoma. Data were collected from surgical records and in telephone interviews with the women. The main outcome was receipt of definitive primary tumor therapy, defined either as modified radical mastectomy or as breast-conserving surgery with axillary dissection followed by radiation therapy. The majority (56%) of the women underwent breast-conserving surgery and axillary dissection followed by radiation therapy. After statistical control for four variables (comorbidity, physical function, tumor size, and lymph node status), patients' ages, marital status, and the number of times breast carcinoma specialists discussed treatment options were significantly associated with the receipt of definitive primary tumor therapy. The authors concluded that when older women have been newly diagnosed with breast carcinoma and there is clinical uncertainty as to the most appropriate therapies, patients may be better served if they are offered choices from among definitive therapies. In discussing therapies with them, physicians must be sensitive to their fears and concerns about the monetary costs and functional consequences of treatment in relation to the expected benefits. *Cancer* 1997;80:1326-34. © 1997 American Cancer Society.

The cumulative risk for breast carcinoma reaches its maximum well into the ninth decade of life. Almost half of all newly diagnosed breast carcinomas occur in women who are age 65 years or older.¹ Although older women are less likely to die of their breast carcinoma than younger women,² recent evidence suggests that older women who do not receive definitive primary tumor therapy are at greater risk of dying from the disease than older women who do receive definitive therapy.³ This finding is particularly important because older women are also at greater risk of not receiving definitive treatment than younger women.⁴⁻¹²

Understanding the reasons why older women do not receive definitive treatment, particularly if the receipt of such treatment results in poorer patient outcomes, is critical if we are to improve such outcomes. Previous investigations have evaluated the potential roles of patients' health status (comorbidity and functional status);^{6,8,11} patients' preferences and their families' preferences and support;^{13,14} and aspects of patient-physician interactions (physicians' attitudes and beliefs^{8,15} and the adequacy of patient-physician communication¹⁶) in explaining age-related treatment variations. For example, when tumor characteristics are taken into account, comorbidity and functional status do not completely explain the tendency of older

women to receive less-than-definitive treatment.^{6,8,11} In addition, married women are more likely to receive definitive therapy than their unmarried counterparts.^{10,13} Finally, physicians who report a greater willingness to involve patients in treatment decision-making tend to be those who recommend breast-conserving surgery without regard to age.¹⁵

In addition to the well-known association, particularly among women, between older age and being unmarried and less-than-definitive therapy,¹⁷ recent literature has documented that the quality of physician-patient interactions decreases with patient age. Physicians tend to spend less time with their older patients than with their younger patients and be less respectful towards their older patients than towards their younger patients. For their part, older patients tend to be less assertive and defer more to their physicians for treatment decisions than their younger counterparts.¹⁸ Whether these features of patient-physician interactions represent cohort effects that will disappear with subsequent generations of physicians and patients is not known. For the present, however, they remain.

Because previous studies of age-related variations in the care of patients with breast carcinoma have not evaluated comprehensively the extent to which patients' ages, marital status, health status (comorbidity and functional status), tumor characteristics, and aspects of physician-patient interactions are independently associated with treatments received, we studied older women newly diagnosed with early stage breast carcinoma and identified factors associated with the receipt of definitive primary tumor therapy. We chose age 55 years as the lower boundary of age eligibility to have a group with which to compare the younger old (ages 65–74 years) and the older old (age 75+ years) age groups. We used a conservative definition of definitive primary tumor therapy (modified radical mastectomy or breast-conserving surgery with axillary dissection followed by radiation therapy), recognizing that there are no specific guidelines for the care of older women with early stage breast carcinoma.

METHODS

Sampling

Women age ≥ 55 years newly diagnosed with histologically confirmed Stage I or II invasive breast carcinoma who had no previous history of other kinds of cancer within the previous 5 years, had no previous history of breast carcinoma, and were cared for at 1 of 5 hospitals with academic affiliation in Boston, Massachusetts, were eligible for study.

To identify potentially eligible patients, project staff reviewed pathology reports at each participating

hospital on a regular basis, beginning in October 1992 and ending in December 1995. Names of potentially eligible patients were faxed to participating surgeons, who confirmed eligibility and also indicated if there were any patients that they did not want us to contact and the reason for this decision. Eligible patients were sent an introductory letter signed by their surgeon and a consent form approximately 2–3 months after initial surgical treatment. This was followed by a telephone call from our interviewer, who further explained the study, answered questions, and obtained informed consent.

Data Collection and Instrumentation

Data were collected via a review of patients' surgical records and a computer-assisted telephone interview with consenting eligible patients.

Medical record abstract

Data collected from medical records included: histology (infiltrating ductal, infiltrating lobular, medullary, mucinous/colloid, or tubular), tumor size (largest diameter of the sum of the largest diameter of all fragments), stage (TNM), estrogen receptor status (positive or negative, according to each laboratory's reference values), the results of axillary dissection if performed, breast surgery performed (mastectomy or breast-conserving surgery), and additional therapies received (radiation therapy, chemotherapy, and/or hormonal therapy). Because the performance of axillary dissection is related to age and we were particularly interested in patterns of care related to age, we chose not to exclude patients who could not be staged based on axillary lymph node pathology. Such women were staged clinically.

Medical records were monitored for 6 months after surgery to determine whether radiation therapy and chemotherapy were initiated and completed, and whether hormonal therapy was initiated. All medical record information was collected by two trained research assistants. A 20% random sample of records abstracted by each research assistant was rereviewed by the other as well as by one of us (R.A.S.). Item interrater reliabilities ranged from 88% to 100%, with most discrepancies occurring early in the study.

Patient interview

The patient telephone interview was conducted an average of 4.5 months after definitive surgery and took 35 minutes to complete. It included questions about demographic characteristics (age, race, marital status, living arrangements, education, employment, and income); cardiopulmonary comorbidity and functional status; factors important in breast carcinoma treat-

ment decision-making, including goals of therapy, side effects of treatment, recommendations of physicians, recommendations of family and friends, and cost; and perceptions of doctor-patient communication. All interviews were conducted by one experienced interviewer.

Major Analytic Variables

Our main outcome variable was definitive primary tumor therapy, defined either as modified radical mastectomy or as breast-conserving surgery with axillary dissection followed by radiation therapy, versus all other primary therapies received (e.g., breast-conserving surgery without radiation therapy).

For our independent variables, we considered variables from four categories. First, we considered demographic characteristics, including age (categorized as ages 55–64, 65–74, and 75+ years, to allow for comparisons among those in late middle age, the younger old, and the older old), marital status (married/not married), and education (<high school/ $\geq$ high school). We did not include income because of the large amount of missing data (24% of subjects did not provide income information).

Second, we considered two measures of health status, because comorbidity and functional status have been shown to contribute unique information to the understanding of the health of older persons.^{19,20} We assessed comorbidity using a continuous measure based on patients' reports of diagnoses of chronic obstructive pulmonary disease, congestive heart failure, ischemic heart disease, and related disease manifestations and symptoms that were part of the Total Illness Burden Index.²¹ The Total Illness Burden Index includes measures of 15 different disease categories and has been shown to be significantly associated with measures of functional status as well as with disability days and the use of health services.²¹ We restricted our assessment of comorbidity to the three disease categories that assess cardiopulmonary disease, because these categories reflect the conditions that are most likely to influence the choice of primary tumor therapy and because we wanted to minimize respondent burden. In the resultant comorbidity measure, a positive score reflects above-average comorbidity.

We assessed physical function using the 10-item physical function subscale of the 36-item short form Medical Outcomes Study functional status questionnaire (SF-36), which is scaled from 0 to 100, with a higher score indicating better function. The SF-36 measures eight health concepts, including physical function, and was developed to represent well-validated, full-length parent scales without loss of statistical precision. Results from the Medical Outcomes

Study indicate that the physical function subscale is reliable and clinically valid.²²

Third, we considered tumor characteristics: tumor size (≤ 1 cm, >1 – 2 cm, >2 cm), estrogen receptor status (positive/negative), and lymph node status (positive/negative). Fourth, we considered patient-physician interactions associated with treatment decision-making: patients' perceptions of doctor-patient communication (a four-item measure that rates the quality of information about breast carcinoma given to patients by their physicians, as well as a physician's ability to give information, discuss treatment options, and tailor treatments to patient needs [Cronbach's $\alpha = 0.92$]), patients' ratings of their physicians' technical and interpersonal care (a four-item measure that rates physicians' personal manner, communication skills, technical skills, and overall care [Cronbach's $\alpha = 0.95$]), and patients' perceptions of their own ability to communicate with their physicians (a three-item measure that assesses patients' ability to give and receive information [Cronbach's $\alpha = 0.96$]). We also asked women about the number of times that breast carcinoma specialists discussed treatment options with them. This latter variable was the sum of affirmative responses to the question, "Did _____ discuss options for your breast carcinoma treatment with you?" This question was asked in relation to up to four breast carcinoma specialists with whom the patient had consulted, including surgeons (also second opinions), medical oncologists, and radiation oncologists. Affirmative responses were 78% for radiation oncologists, 83% for surgeons who performed the diagnostic biopsy (98% for second opinion surgeons), and 87% for medical oncologists. Finally, we asked whether family members were involved in the treatment decision-making process.

Analytic Strategy

Descriptive statistics were obtained for all study variables. We then performed a series of bivariate analyses, examining the relationships between each independent variable and the dependent variable, using two independent sample Student's *t* tests and chi-square tests as appropriate. Our bivariate analyses were performed using a three-level form of the dependent variable (radical mastectomy vs. breast-conserving surgery/axillary dissection/radiation therapy vs. all other therapies) to appreciate better the differences across these categories of primary tumor therapy.

In our multiple logistic regression analysis, we used a two-level form of the variable (definitive primary tumor therapy vs. all others) for four major reasons: 1) the majority of our subjects underwent breast-conserving surgery with axillary dissection followed by

radiation therapy; 2) modified radical mastectomy and breast-conserving surgery with axillary dissection followed by radiation therapy have been demonstrated to be equivalent with respect to mortality;²³ 3) as noted above, recent data suggest that older women who receive less-than-definitive treatment are more likely to die of their breast carcinoma than older women who receive definitive treatment;³ and 4) logistic regression models with more than a two-level dependent variable are often difficult to interpret.

We took a conservative approach to developing our logistic regression model. Because of the importance of comorbidity, functional status, tumor size, and lymph node status in clinical decision-making, we forced these variables into our model. We then used stepwise multiple logistic regression techniques, with a significance criterion of 0.05 for entry or removal from the model for all other variables identified as being statistically significant on bivariate analysis.

Finally, in an effort to understand the results of our logistic regression analysis, we also performed a series of exploratory bivariate analyses, relating patients' ages and marital status to factors identified by the patients as being important in their decision-making about their breast carcinoma treatment.

RESULTS

Study Sample

Three hundred eighty-eight eligible patients were identified whose surgeons gave permission for contact. Of these, 302 (78%) agreed to participate. Patients who did not participate declined ($n = 40$), could not be contacted ($n = 25$), were in ill health ($n = 13$), or were non-English-speaking without a translator available ($n = 8$). Nonparticipants were an average of 3 years older than participants (71.2 vs. 68.4 years, $P = 0.01$). Equal proportions of participants and nonparticipants had Stage I (78%) and Stage II (22%) disease, respectively. No other information about nonparticipants was available.

Patient characteristics are displayed in Table 1. A little over half of our subjects were age ≥ 65 years (range, 55–97 years), and most were white. Half were married; most of the remainder were widowed. The majority had a high school education or greater. Their average comorbidity score was 7.06 (range, 3–20). The majority of patients had infiltrating ductal carcinoma and had Stage I disease. Stage I patients tended to be slightly older than Stage II patients (mean age, 68.9 vs. 66.6 years). In addition, older patients were more likely to be estrogen receptor positive (72% of patients age 55–64 years, 74% of those age 65–74 years, and 86% of those age 75+ years).

TABLE 1
Patient Demographics and Clinical Characteristics (n = 302)^a

Characteristic	No. of patients (%)
Demographics	
Age (yrs)	
55–64	123 (41)
65–74	111 (37)
75+	65 (22)
Race	
White	280 (94)
African American	13 (4)
Other	7 (2)
Marital status	
Married	148 (49)
Widowed	98 (33)
Single	23 (8)
Divorced/separated	30 (10)
Education	
<High school	51 (17)
High school graduate	107 (36)
>High school	141 (47)
Health status	
Comorbidity (mean $\pm$ SD)	7.06 $\pm$ 2.4
Physical function (mean $\pm$ SD)	73.75 $\pm$ 21.61
Tumor characteristics	
Histology	
Infiltrating ductal	259 (86)
Infiltrating lobular	31 (10)
Other	12 (4)
Tumor size	
≤ 1 cm	85 (31)
>1–2 cm	128 (46)
>2 cm	65 (23)
Lymph node status	
Negative	241 (80)
Positive	60 (20)
Estrogen receptor status	
Positive	209 (76)
Negative	67 (24)
Primary tumor therapy	
Breast-conserving surgery/axillary dissection/ radiation therapy	169 (56)
Modified radical mastectomy	65 (21)
Other	
Breast-conserving surgery/radiation	26 (9)
Breast-conserving surgery/axillary dissection	22 (7)
Breast-conserving surgery alone	10 (3)
Miscellaneous	10 (3)

SD: standard deviation.

^a Because values are missing, not all categories add up to 302.

Treatment Priorities

We asked our subjects about factors that were important in their decision-making. Two factors were rated very important by almost all patients (100% and 96%, respectively): 1) minimizing the possibility of recurrence, and 2) their doctors' recommendations. Although there was less consensus, also very important

to the majority were quality of life after treatment (77%) and their family's opinion (52%). A substantial minority also rated as very important what they would have to pay over and above what their insurance would cover and problems they would experience after surgery (28% and 22%, respectively). In contrast, 3 treatment-related factors were rated as *not* important at all by the majority of patients: 1) effects of treatment on sexuality (83%), 2) difficulty getting to and from treatments (65%), and 3) effects of treatment on looks (63%).

Predictors of Definitive Primary Tumor Therapy

In contrast to patterns of care observed elsewhere among older women with breast carcinoma,^{8,10-12} the majority of women in our study underwent breast-conserving surgery and axillary dissection followed by radiation therapy (Table 1). Less than a quarter received a modified radical mastectomy. The remaining quarter received 1) breast-conserving surgery and radiation therapy, but no axillary dissection ($n = 26$); 2) breast-conserving surgery and axillary dissection, but no radiation therapy ($n = 22$); 3) breast-conserving surgery alone ($n = 10$); or 4) other ($n = 10$), such as radiation therapy only, incisional biopsy only, or simple mastectomy with or without radiation therapy.

The bivariate relationships between each of the independent variables and primary tumor therapy, categorized as modified radical mastectomy, breast-conserving surgery with axillary dissection followed by radiation therapy, or other therapies, are displayed in Table 2. Age, marital status, education, physical function, tumor size, lymph node status, and the number of times breast carcinoma specialists discussed treatment options were each significantly associated with the type of primary tumor therapy received ($P < 0.05$).

To understand the independent contributions of variables identified as statistically significant on bivariate analysis, we developed a multiple logistic regression model (Table 3) that controlled for comorbidity, physical function, tumor size, and lymph node status. Patient age, marital status, and the number of times breast carcinoma specialists discussed treatment options were independently and significantly associated with the receipt of definitive primary tumor therapy (modified radical mastectomy or the combination of breast-conserving surgery, axillary dissection, and radiation therapy). Older women, women who were not married, and women with whom treatment options were discussed less frequently were *less likely* to receive definitive primary tumor therapy, after taking into account differences in health status and tumor characteristics.

In an attempt to understand whether patient pref-

erences were the reasons why age and marital status remained significant predictors of primary tumor therapy after statistical control for such potentially important confounders as comorbidity, physical function, tumor size, and lymph node status, we performed a series of bivariate analyses, relating patients' ages and marital status to factors identified by them as being important in their decision-making about their breast carcinoma treatment. With respect to age, the only issue of importance that differed by age was whether women had other responsibilities, such as caring for other family members. About 20% of women among those ages 55-64 years and among those ages 65-74 years indicated that this was a very important consideration, whereas only 7% of the group age 75+ years indicated that it was very important ($P < 0.01$). In fact, 83% of the group age 75+ years indicated that this consideration was not important at all.

Three factors related to marital status emerged as being important in women's treatment decision-making. Women who were not married were more likely to indicate that the problems they would experience after surgery ($P < 0.05$) and what they would have to pay over and above what their insurance would cover ($P < 0.01$) were very important considerations in their treatment decision-making. In contrast, married women, as with younger women, reported that having other responsibilities was a very important consideration ($P < 0.01$).

DISCUSSION

In this study of age-related variations in the treatment of patients with early stage breast carcinoma in the 1990s, we found that the majority (56%) of women underwent breast-conserving surgery and axillary dissection followed by radiation therapy. This percentage is higher than that observed even among younger women^{10,12} and is in keeping with the fact that the Northeast has among the highest rates of breast-conserving surgery in the United States, even among older women.^{24,25} In addition, age, marital status, and an indicator of patient-physician interactions (the extent to which breast carcinoma specialists discussed treatment options) were all independently associated with the receipt of definitive primary tumor therapy by older women with early stage breast carcinoma. These associations persisted after statistical control for comorbidity, physical function, and relevant tumor characteristics.

The inability of these latter factors to explain completely the age-related treatment variations in breast carcinoma care is in agreement with the findings of other investigators but requires explanation.^{6,8,11,26} It is possible, for example, that we inadequately con-

TABLE 2
Factors Associated with Primary Tumor Therapy (n = 302)

Factors	No. of patients (%)		
	Modified radical mastectomy	Breast-conserving surgery/AD/RT	Other therapies
Demographics			
Age ^a			
55-64	34 (28)	77 (62)	12 (10)
64-74	20 (18)	73 (66)	18 (16)
75+	11 (17)	17 (26)	37 (57)
Marital status ^a			
Married	37 (25)	93 (63)	18 (12)
Not married	28 (19)	75 (49)	49 (32)
Education ^a			
<High school	8 (16)	22 (43)	21 (41)
≥High school	57 (23)	146 (59)	45 (18)
Health status (mean score)			
Comorbidity	6.91	7.03	7.27
Physical function ^a	72.46	76.69	67.22
Tumor characteristics			
Tumor size ^a			
≤1 cm	8 (9)	53 (62)	24 (28)
>1-2 cm	16 (12)	79 (62)	33 (26)
>2 cm	29 (45)	29 (45)	7 (10)
Estrogen receptor status			
Positive	42 (20)	122 (58)	45 (22)
Negative	19 (28)	37 (55)	11 (17)
Lymph node status ^a			
Negative	43 (18)	134 (56)	64 (26)
Positive	22 (37)	35 (58)	3 (5)
Patient-physician interaction (mean score)			
Doctor-patient communication	93.17	92.05	92.19
Technical and interpersonal care	95.29	94.90	96.15
Perceptions of abilities to communicate	71.28	71.90	67.76
No. of times treatment options were discussed ^a	2.6	2.23	2.1
Family member participation in treatment decision-making			
Yes	21 (23)	57 (64)	12 (13)
No	44 (21)	112 (55)	50 (24)

AD: axillary dissection; RT: radiation therapy.

^a $P < 0.05$.

trolled for variations in health status and tumor prognostic factors in our multiple logistic regression model. We relied on women's reports of cardiopulmonary diseases and symptoms for our measure of comorbidity and on their reports of the physical limitations that were due to their health. However, recent studies from Europe have documented that older patients can accurately report whether or not they have cardiovascular disease,^{27,28} and our measure of physical function has been used widely in studies of older persons and has been shown to be sensitive to low levels of morbidity.^{29,30} Furthermore, in our study, older women reported more comorbidity and poorer physical function than younger women, as would be expected (Table 1). Finally, we performed an addi-

tional multiple logistic regression analysis, excluding women age 75+ years with very small tumors (<1 cm). In this analysis, age persisted as an independent predictor of definitive primary tumor therapy.

We believe that clinical uncertainty as to the most appropriate therapies for older women affords the best explanation for the age-related variations that we have observed. In particular, there is controversy about the necessity of axillary dissection as well as that of radiation therapy following breast-conserving surgery for older women. Questions about axillary dissection relate to its diagnostic versus therapeutic value;³¹ questions about postoperative radiation therapy arise because it has not been demonstrated to affect survival rates and also because it may not be necessary for

TABLE 3
Multiple Logistic Regression Model Predicting Receipt of Definitive Primary Tumor Therapy^a

Variable	β -coefficient	Odds ratio (95% CI)
Tumor size		
≤1 cm (referent)	—	—
>1-2	0.2948	1.34 (0.62, 2.89)
>2	1.5372	4.65 (1.48, 14.65)
Lymph node status (positive/negative)	1.3265	3.77 (1.02, 13.95)
Age group		
55-64 yrs	2.3032	10.01 (3.78, 26.47)
65-74 yrs	1.8580	6.41 (2.68, 15.35)
75+ yrs (referent)	—	—
Marital status (married/not married)	0.8961	2.45 (1.17, 5.15)
No. of times treatment options were discussed (continuous)	0.5423	1.72 (1.14, 2.61)

CI: confidence interval.

^aAdjusted for comorbidity and physical function.

achieving acceptably low recurrence rates in older women.³²⁻³⁴ It is clear from our data and those of others that axillary dissection and radiation therapy are being used preferentially less often in older women than in younger women. Among our patients, adjuvant systemic therapy (usually tamoxifen) appears to have been substituted for these procedures in about two-thirds of women who did not receive standard primary therapy. Whether this substitution results in similar outcomes is not known definitively, although there is case-series evidence suggesting that this strategy may be appropriate for older women with T1 tumors.^{35,36}

Our findings confirm and extend the work of previous investigators who have found that being unmarried is a risk factor for not receiving definitive therapy for breast carcinoma.^{10,13}

The older unmarried women in our study were more concerned than married women about treatment-related problems that they might experience after surgery and the out-of-pocket costs of their care. Both of these concerns may have led them to choose less intense primary tumor therapy regimens. Whether their surgeons tended to offer such regimens preferentially to them is not known.

In this regard, an important finding in our study was the influence of the extent to which treatment options were discussed regarding the primary tumor therapies received by older women. Others have found that older women are less likely to receive medical or radiation oncologist consultations^{7,37} and that being offered a choice is more strongly related to psychosocial outcomes than is the type of treatment.³⁸ We believe that if patients are offered choices and are encouraged to be involved in their care, the decisions

that they and their physicians make may more closely reflect their own values and preferences. When they are not, the decisions made may more closely reflect the values and beliefs of their physicians. Here, clinical uncertainty (or biases) about what represents appropriate care may have an important influence on physician-directed decisions.

Our findings are provocative, but they must be interpreted with the following limitations in mind. First, we studied the care of women who were mainly white, well-educated, and older in clinical settings with academic affiliations in one geographic region (Boston, Massachusetts). Second, selection factors resulted in our studying younger members, on average, of the eligible patient population. However, we believe that studies of older and more diverse patient populations may find an even larger impact of age, marital status, and patient-physician interactions on outcomes than we did. Third, we relied on women's recall of events and treatment decision-making that had occurred several months previously. Details of physician visits and thought processes may have been forgotten or recalled imperfectly. It seems unlikely, however, that this should have occurred differentially across treatment groups. Finally, our measure of the extent to which treatment options were discussed was based on counts of reported discussions rather than an actual measure of the depth and extent of discussions, such as would be available from audio or videotaping or from direct observation.

With these limitations in mind, it is clear that additional studies are needed that focus on both the process and the outcomes of care for older women with breast carcinoma. Such studies must take into account comorbidity, functional status, and tumor characteristics, and must link therapies received with the important clinical outcomes of functional status, breast carcinoma recurrence, and breast carcinoma specific mortality. Such studies are particularly important because the most recent breast carcinoma mortality figures demonstrate a marked decline in mortality in all age groups except those age 80 years or older. Furthermore, the mortality rate in those ages 70-79 years did not decline between 1991 and 1993, as it did in every younger age group.³⁹

It is noteworthy that almost all of the women in this study reported that minimizing the possibility of recurrence their doctors' recommendations were both very important considerations in their treatment decision-making. Our older patients may therefore be better served if we recommend definitive therapies or recommend that they participate in clinical trials and/or observational studies designed to answer the critical questions of treatment efficacy and effectiveness in

older persons. In discussing therapies with them, we must be sensitive to their fears and concerns about the monetary costs and functional consequences of treatment in relation to the expected benefits.

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Breast Cancer Care in Older Women

Sources of Information, Social Support, and Emotional Health Outcomes

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BACKGROUND. The authors studied older women with breast cancer and asked: 1) where do older women get information regarding breast cancer care and how helpful do they perceive each of these sources to be? and 2) what aspects of social support are associated with older women's general and breast cancer specific emotional health outcomes?

METHODS. To be eligible, women had to be at least 55 years of age and newly diagnosed with TNM Stage I or II breast cancer. Data were collected from women's surgical records and a 35-minute, computer-assisted telephone interview.

RESULTS. Nearly all women rated information that was provided by their breast cancer physicians as very or somewhat helpful. Written materials provided by breast cancer physicians also were frequently rated as very or somewhat helpful. Women's marital status, religious service attendance, ratings of their physicians' technical and interpersonal care, and perceptions of their own abilities to communicate with their physicians were significantly associated with both general and breast cancer specific emotional health outcomes (all $P < 0.05$).

CONCLUSIONS. Although older women obtained information regarding breast cancer from a variety of sources, they relied heavily on their physicians for information. To care most effectively for this group of patients, an increased understanding of the relation between the processes and outcomes of breast cancer care is needed. Identifying older women with breast cancer at risk for poor emotional health outcomes and developing methods to enhance physician-patient communication in this setting may improve these outcomes. *Cancer* 1998;83:706–11.

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KEYWORDS: older women, breast cancer, emotional health, physician-patient communication.

Sixty percent of incident cases of breast cancer are diagnosed in women age ≥ 60 years.¹ This percentage is likely to grow, not only because older age is the most important risk factor for breast cancer, but because of gains in life expectancy and decreases in deaths due to cardiovascular disease. To most effectively care for this growing group of women, we need to understand the relation between the processes and outcomes of breast cancer care.

Over the past decade, investigators who have focused on age-related variations in breast cancer care have documented that older women are at greater risk for receiving less than definitive treatment.^{2–10} We recently reported that, in addition to older age, being unmarried and having treatment options discussed less frequently also are risk factors for the receipt of less than definitive primary tumor therapy.¹⁰ Newer studies suggest that the receipt of less than definitive care is associated with both higher recurrence rates and higher mortality rates among older women.^{11,12}

In contrast, comparatively less attention has been paid to the relation between processes of care and quality-of-life outcomes among older women. As the proportion of older women who are longer term survivors of breast cancer continues to grow, this relation will assume greater importance, particularly if it is demonstrated that variations in the process of care are related to variations in these quality-of-life outcomes. Although older women are in general at lower risk for adverse psychosocial outcomes than are their younger counterparts,¹³⁻¹⁵ there are reasons to believe that some older women may be at higher risk because of inadequate social support, including poor communication between them and their physicians. First, older women frequently are single; 36% of women ages 65-74 years, 62% of women ages 75-84 years, and 80% of women age ≥ 85 years are widowed. In addition, the majority of women age ≥ 75 years live alone.¹⁶ Second, although religious involvement appears to have a protective effect among older women with respect to depression, the converse also is true: older women with less religious involvement are at greater risk of depression.¹⁷ Third, physicians tend to spend less time with their older patients than they spend with their younger patients.^{18,19} In addition, they tend to be more egalitarian and provide better information, questioning, and support to their younger patients than to their older patients.²⁰ A recent study of older and younger breast cancer patients has documented similar findings.²¹ And in studies of patients with various chronic diseases, a more participatory decision-making style of care on the part of their physicians (e.g., presenting options, discussing the pros and cons of these options, and eliciting patient preferences) has been associated with better functional and physiologic outcomes.²²

With these considerations in mind, we studied older women with early stage breast cancer and asked the following questions: 1) where do older women receive information regarding breast cancer care and how helpful do they perceive each of these sources to be? and 2) what aspects of social support are associated with older women's general and breast cancer specific emotional health outcomes?

METHODS

Study Sample

The study's methods have been described elsewhere.¹⁰ To be eligible for the study, women had to be age ≥ 55 years, newly diagnosed with TNM Stage I or II breast cancer, and have no previous history of breast cancer. Eligible women were sent an introductory letter and a consent form 2-3 months after their definitive surgical treatment. Our interviewer conducted

follow-up by telephone, providing additional information regarding the study, answering questions, and obtaining informed consent.

Data Collection

Data were collected from women's surgical records and a 35-minute, computer-assisted telephone interview with consenting women. Data collected from medical records included: histology, stage, and surgeries performed (modified radical mastectomy or breast-conserving surgery). The patient telephone interview, conducted an average of 4.5 months after definitive surgical therapy, included questions regarding sociodemographic characteristics (including age, education, marital status, and religious service attendance); general health-related quality of life (as measured by the Medical Outcomes Study Short Form [SF-36]²³); breast cancer specific quality of life (with response options ranging from excellent [1] to poor [5]); the presence of physician-diagnosed cardiopulmonary diseases and the frequency of associated symptoms; the perceived helpfulness of various sources of information regarding breast cancer and its treatment (with response options ranging from very helpful [1] to not applicable, did not get information from this source [5]); the kinds of help that they did not have, but wished that they had to assist them with treatment decision-making; and ratings of their breast cancer specialists' technical and interpersonal care (with response options ranging from excellent [1] to poor [5]).

Major Analytic Variables

Outcome Variables

We considered two dependent variables in our analyses: 1) general emotional health, a 5-item measure of emotional health from the Medical Outcomes Study SF-36²³ that is scaled from 0-100, with a higher score indicating better emotional health (Cronbach's $\alpha = 0.83$), and 2) breast cancer specific emotional health, a 4-item measure of feelings and worries due to potential problems associated with the progression of breast cancer, again scaled from 0-100, with a higher score indicating better breast cancer specific emotional health (Cronbach's $\alpha = 0.78$). The four breast cancer specific items were: *Now that much of your treatment is behind you, how well do you feel you are doing with each of the following:* 1) *Dealing with feelings such as anger, fear, grief, and anxiety;* 2) *Worries about your family's ability to manage if you get sicker;* 3) *Worries about who will take care of you if you get sicker;* and 4) *Worries about recurrence of the cancer.*

Independent Variables

We considered indicators of social support from two categories: 1) women's informal social support: marital status (married/not married) and attendance at religious services (approximately once a week or more/lesser amounts); and 2) physician-patient communication associated with treatment decision-making: patients' perceptions of physician communication (a 4-item measure based on ratings of the quality of breast cancer information given to patients by their physicians, as well as physicians' abilities to give information, discuss treatment options, and tailor treatments to patient needs [Cronbach's $\alpha = 0.92$]); patients' ratings of their physicians' technical and interpersonal care (a 4-item measure based on ratings of physicians' personal manner, communication skills, technical skills, and overall care [Cronbach's $\alpha = 0.95$]); and patients' perceptions of their own abilities to communicate with their physicians (a 3-item measure based on patients' ratings of their abilities to get information from, and to give information to their physicians [Cronbach's $\alpha = 0.96$]). All physician-patient communication variables were scaled from 0–100, with higher scores indicating better ratings.

Covariates

We considered age, two measures of health status (comorbidity and perceptions of change in health status), and type of surgery as covariates. We divided age into three categories: 55–64 years, 65–74 years, and 75+ years. We assessed comorbidity using a continuous measure that ranged in score from 3–20 and was based on patients' reports of diagnoses of chronic obstructive pulmonary disease, congestive heart failure, and ischemic heart disease and related disease manifestations and symptoms that were part of the Total Illness Burden Index.²⁴ We also included women's perceptions of change in their health status during the previous year (an item from the SF-36).²³ This measure was scaled from 0–100 with a higher score indicating better health status. Type of surgery was classified as modified radical mastectomy versus breast-conserving surgery.

Analytic Strategy

We first obtained descriptive statistics on all study variables, which allowed us to address our first study question regarding the sources of information about breast cancer accessed by women and their perceived helpfulness. We also assessed the relation between each source of information and women's age, education, and marital status using chi-square tests. We then identified factors associated with patients' gen-

eral and breast cancer specific emotional health outcomes. In the first phase of the analysis we investigated the distributional properties of our two dependent variables and our array of independent variables. Next, we examined bivariate relations between the independent variables and each dependent variable using two independent sample Student's *t* tests and correlation analysis. We selected independent variables for potential inclusion in regression models based on significance with each dependent variable ($P < 0.05$). Once a pool of candidate-independent variables was identified, bivariate relations between the independent variables were examined to assess multicollinearity. In the final stage of the analysis we developed multiple linear regression models relating the two dependent variables, considered separately, to selected independent variables.

RESULTS

Study Sample

Three hundred eighty-eight eligible women were identified, 302 of whom (78%) agreed to participate. They ranged in age from 55–97 years. Nearly half were married (49%) and nearly one-third (34%) attended religious services once or more per week. Mean scores on health status indicators were as follows: comorbidity = 7.06 (range, 3–20); health transitions = 44.95 (range, 0–100); general emotional health = 74.01 (range, 12.5–100); and breast cancer specific emotional health = 65.95 (range, 6.25–100). Twenty-one percent of these women underwent modified radical mastectomy.

Perceived Helpfulness of Sources of Information Regarding Breast Cancer

When asked about the helpfulness of breast cancer-related information received from a variety of sources, the information that was provided by their breast cancer physicians was rated as very or somewhat helpful by nearly all women (Table 1). Written materials provided by breast cancer physicians also were frequently rated as very or somewhat helpful. Of less perceived helpfulness was written information obtained from sources other than their breast cancer physicians, and information provided by friends and family, by television specials, and by primary care physicians. Note that substantial numbers of women did not access information from these latter four sources. When we restricted the analysis to only those who actually obtained information from a given source, all ratings improved. However, their rank ordering changed very little, with the exception that television specials were rated slightly lower than primary care physicians (see Table 1, percentages in brackets).

TABLE 1
Sources of Information Regarding Breast Cancer (n = 302)

Source	Very or somewhat helpful No. (%) [%] ^a	Perceived helpfulness	
		Not very or not helpful at all No. (%)	Not applicable (did not get information from this source) No. (%)
Breast cancer physicians or staff	294 (99)[99]	2 (1)	0
Written materials from breast cancer physician	248 (84)[95]	12 (4)	36 (12)
Other written materials obtained by patient	198 (67)[92]	17 (6)	81 (27)
Friends and family	161 (54)[84]	30 (10)	105 (36)
Television specials	139 (47)[68]	65 (22)	92 (31)
Primary care physician	120 (41)[72]	46 (15)	130 (44)

^a Second percentage shown is a recalculation of the percentage that excludes the responses from the category "Not Applicable."

We also examined the relation between age, education, and marital status and women's ratings. The oldest women (age 75+ years) were most likely not to have obtained written information from sources other than their breast cancer physicians (43% vs. 33% of those ages 65–74 years, and 15% of those ages 55–64 years; $P = 0.001$) or from friends and family (50% vs. 38% of those ages 65–74 years, and 27% of those ages 55–64 years; $P = 0.04$). When we restricted the analysis to those who actually obtained information from these sources, the youngest group of women (ages 55–64 years) were more likely to have found the written information that they had obtained to be very or somewhat helpful (98% vs. 89% of those ages 65–74 years, and 79% of those age 75+ years; $P = 0.001$); there was no difference by age with respect to the perceived helpfulness of information from friends and family. Educational attainment and marital status were not related to whether information was obtained from a particular source, nor its perceived helpfulness.

When asked about the kinds of help with treatment decision-making that they did not have but wished that they had, 60% of women wished that they had someone with them at appointments when treatment options were discussed; 39% wished that they had help with knowing what questions to ask.

Women's General and Breast Cancer Specific Emotional Health

To determine whether women's informal social support and aspects of physician-patient interactions were related to their general and breast cancer specific emotional health, we developed separate multiple regression models. We included age and type of surgery as independent variables in the models but they did not add statistically or substantively, and therefore were removed from the models.

With general emotional health as the dependent

TABLE 2
Results of Multiple Regression Analysis: General Emotional Health^a

Independent variable	Standardized parameter estimate	P value
Marital status	0.1495	0.008
Religious service attendance	0.1418	0.011
Physician's interpersonal and technical care	0.1381	0.016
Patient's ability to communicate with her physician	0.1184	0.04

^a Adjusted for comorbidity and change in health status.

R square = 0.16.

TABLE 3
Results of Multiple Regression Analysis: Breast Cancer Specific Emotional Health^a

Independent variable	Standardized parameter estimate	P value
Marital status	0.1865	0.0009
Religious service attendance	0.1124	0.042
Physician's interpersonal and technical care	0.1594	0.006
Patient's ability to communicate with her physician	0.1636	0.005

^a Adjusted for comorbidity and change in health status.

R square = 0.16.

variable and controlling for comorbidity and change in health status in the previous year, women's marital status, their religious service attendance, their ratings of physicians' technical and interpersonal care styles, and their perceptions of their own abilities to communicate with their physicians were statistically significant (Table 2). Similarly, with breast cancer specific emotional health as the dependent variable and controlling for comorbidity and change in health status, the same four variables also were statistically signifi-

cant (Table 3). With the exception of regular religious service attendance, the relations between the independent variables and breast cancer specific emotional health were stronger than those between independent variables and general emotional health.

DISCUSSION

Consistent with the published literature,²⁵ we found that older women value highly the information provided by their breast cancer physicians. In addition, the women that we studied, particularly the youngest women (those ages 55–64 years), accessed other sources of information that most considered to be of value, presumably because these sources complemented and reinforced information provided by their physicians.²⁶ Of concern, these women perceived their primary care physicians to be one of the least helpful sources of information regarding breast cancer care. As our nation moves toward models of care that increasingly rely on primary care physicians, these front-line physicians will need to have access to up-to-date, high quality information regarding cancer care appropriate for different subsets of patients. Furthermore, if primary care physicians are to provide the majority of follow-up care for breast and other cancer survivors, they must understand treatment as well as follow-up care issues.²⁷ This information will be particularly important for older women, because these women are more likely to have a greater burden of comorbid illness and functional disability. They also are more likely to have long-standing relations with their primary care physicians than with their breast cancer physicians.

In addition, the circumstances surrounding breast cancer treatment decision-making appear to have been suboptimal for a substantial proportion of women. They indicated that they would have benefited from having someone with them at appointments when treatment options were discussed and from having help with knowing what questions to ask in relation to breast cancer and its treatment. In this regard, it is noteworthy that women's perceptions of their abilities to communicate with their physicians were statistically significantly associated with both general and breast cancer specific emotional health. Women who rated their abilities less highly had lower emotional health scores, even after controlling for health status and other social support indicators.

The setting of newly diagnosed breast cancer probably is not the best time to try to enhance patients' abilities to communicate with their physicians. Furthermore, it is not clear whether communication skills learned in the setting of chronic disease care can be translated to an acute crisis situation. Nonetheless,

awareness of women's insecurities with their communication skills, in addition to the presence of other risk factors for adverse outcomes, may help target those women who might benefit most from the extra time and effort required to involve them to a greater extent in the treatment decision-making process. Our regression models suggest that these other risk factors may include being unmarried and not being an active participant in a religious community. Indeed, the associations that we found between marital status and religious service attendance and our emotional health measures are consistent with previous literature documenting the benefits of social support²⁸ and add to the growing body of literature documenting the positive relation between religious service attendance and health outcomes.²⁹

The additional positive association between patients' ratings of their physicians' technical and interpersonal care and our two measures of emotional health further emphasize the critical importance of physician-patient communication in the management of breast cancer in older women. As noted earlier and as documented by others, older patients frequently rely on their physicians to make treatment decisions for them.³⁰ Physicians may need to work harder to involve their older patients in care decisions than their younger patients, particularly those who have additional insecurities regarding their own communication skills and those who lack social support. The challenges associated with this effort are considerable, especially given current pressures to decrease rather than increase the amount of time physicians spend with patients.³¹ However, the benefits are likely not only to improve decision-making with respect to treatment,¹⁰ but with regard to better emotional health outcomes as well.¹⁵

Our study has several limitations that must be taken into account when interpreting its findings. First, we studied largely white, well educated older women in clinical settings with academic affiliations in one geographic region. Second, differential response rates resulted in our studying younger members, on average, of the eligible patient population. Both factors limit our ability to generalize our results. However, in this regard it is difficult to know whether the observed relations might have been stronger or weaker had we been able to study a more heterogeneous sample.

Third, our data are cross-sectional and therefore preclude definitive statements regarding cause and effect. Fourth, we relied on self-reported recalled information because we were neither able to observe directly physician-patient encounters nor to audio-tape or videotape them. Nonetheless, we believe that

our findings support several conclusions. Although women obtain information regarding breast cancer from a variety of sources, they rely heavily on their physicians for information on breast cancer and its treatment. Given clinical uncertainty as to what represents the most appropriate therapy for older women, we believe that it is all the more important that physicians offer them choices so that their decisions reflect their values and preferences.¹⁰ In addition, identifying older women with breast cancer at risk for poor emotional health outcomes and developing methods to enhance physician-patient communication in this setting may improve these outcomes.

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RISK FACTORS FOR A DECLINE IN UPPER BODY FUNCTION FOLLOWING
TREATMENT FOR EARLY STAGE BREAST CANCER

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Running Title: Function Following Breast Cancer Treatment

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Summary

Purpose: To identify risk factors for a decline in upper body function following treatment for early stage breast cancer.

Methods: We conducted a cross-sectional observational study of 215 women ≥ 55 years of age newly diagnosed with early stage breast cancer interviewed three to five months following their definitive surgery. Patients were classified as having impaired upper body function related to their breast cancer treatment if: 1) they reported having no difficulty in performing any of three tasks requiring upper body function (pushing or pulling large objects; lifting objects weighing more than 10 pounds; and reaching or extending arms above shoulder level) prior to treatment, but reported that any of these tasks were *somewhat* or *very* difficult in the four weeks prior to interview, or 2) they reported that performing any of the three tasks requiring upper body function was *somewhat* difficult prior to treatment, but reported that any of these tasks were *very* difficult in the four weeks prior to interview.

Results: In multiple logistic regression models, both the extent and type of primary tumor therapy and cardiopulmonary comorbidity were significantly associated with a decline in upper body function following breast cancer treatment.

Conclusion: Given the critical importance of upper body function in maintaining independent living, clinicians should consider the functional consequences of treatment when they discuss treatment options and post-operative care with older women who have early stage breast cancer.

Key words: Upper body function, older women, breast cancer treatment

Introduction

Breast cancer has become increasingly common among older women. The incidence of breast cancer increases with age until at least the ninth decade of life, the number of older women at-risk has increased, and the age-adjusted incidence has increased, in part due to increased use of screening mammography (1). Furthermore, the increasing use of screening mammography has resulted in a greater proportion of older women being diagnosed with early stage disease (2). Earlier diagnosis, coupled with an overall increase in longevity in late life, will likely result in an increase in the number of older women who are long-term survivors of breast cancer. For these women, the functional consequences of breast cancer treatment, manifested in tasks that require upper body strength, are likely to assume greater importance, particularly as they concomitantly acquire age-related disabilities.

Satariano and colleagues studied the functional consequences of breast cancer therapy and found that among women aged 55-74 who were treated for breast cancer, at three months following diagnosis they were more likely than controls without breast cancer to report difficulty in completing tasks that required upper body strength (3). In another study by the same investigative team, analyses conducted with the case group failed to find a treatment effect. However, the treatment measure categorized radiation, chemotherapy, and hormonal therapy together as "adjuvant therapy". Thus, it was not possible to evaluate the effects of standard therapies nor of the specific components of these therapies on upper body function (4).

Because tasks that require upper body strength are crucial for maintaining independence, it is important to identify risk factors for breast cancer patients' decline in abilities to perform such tasks. Knowledge of these risk factors may aid in the identification of women at high risk for poor functional outcomes and in the choice of their primary breast cancer treatment.

We therefore conducted a cross-sectional study of women ≥ 55 years of age at three to five months after their treatment for newly diagnosed stage I and stage II breast cancer to identify risk factors for a decline in upper body functional abilities in relation to treatments received.

Methods

Sampling

Details of the study have been described elsewhere (5). In brief, we studied women ≥ 55 years of age, newly diagnosed with histologically confirmed stage I and stage II invasive breast carcinoma cared for at one of five hospitals in Boston, Massachusetts. Potential study participants were sent an introductory letter signed by their surgeon and a consent form at approximately two to three months following their definitive surgical treatment. An interviewer followed-up with a telephone call to explain the study further, to answer questions, and to obtain informed consent. We restricted the analyses described herein to those women interviewed three to five months following their definitive surgery to minimize variation associated with differing lengths of recovery time.

Data Collection

Data were collected via a review of patients' surgical records and a 35 minute computer-assisted telephone interview with consenting eligible patients. Data collected from medical records included: tumor size, axillary node status, breast surgery or surgeries performed (mastectomy or breast conserving surgery, with or without axillary dissection), and whether or not the patient received a course of post-operative radiation therapy. The patient telephone interview included questions about tasks that required upper body function and were asked in relation to breast cancer treatment: 1) pushing or pulling large objects, such as a living room chair, 2) lifting objects weighing more than 10 pounds, such as a heavy bag of groceries, and 3) reaching or extending arms above shoulder level. For each task, the subject was asked about its difficulty (*very, somewhat, or not difficult*) in performance during four weeks preceding interview as well as prior to their breast cancer treatment. These items were selected from the

items used by Satariano and colleagues (3), fielded previously in the Framingham Disability Study (6) and derived from the original work of Nagi (7). In addition, we asked questions about cardiopulmonary comorbidities that were part of the Total Illness Burden Index (8), as well as about demographic characteristics (age, race, marital status, education, height, and weight).

Major Analytic Variables

Our dependent variable was a decline in upper body function in relation to breast cancer treatment. Patients were classified as having a decline in upper body function in relation to their breast cancer treatment if: 1) they reported having no difficulty in performing any of the three tasks requiring upper body function prior to treatment, but reported that any of these tasks were *somewhat* or *very* difficult in the four weeks prior to interview, or 2) they reported that performing any of the three tasks requiring upper body function was *somewhat* difficult prior to treatment, but reported that any of these tasks were *very* difficult in the past four weeks.

For our independent variables we considered: age (55-64, 65-74, 75+ years) and education (< high school/ $\geq$ high school). We also considered body mass index (BMI: weight in kilograms divided by height in meters squared); comorbidity (a continuous measure based on patients' reports of diagnoses of chronic obstructive pulmonary disease, congestive heart failure, and ischemic heart disease and related symptoms, with a positive score reflecting above average comorbidity); breast cancer characteristics, including tumor size (≤ 1 cm, $>1-2$ cm, > 2 cm) and node status (positive/negative); and breast cancer treatments received. For the breast cancer treatments variables, we used two different approaches. First, we considered each of the two standard treatments (modified radical mastectomy and breast conserving surgery with axillary dissection followed by radiation therapy) in comparison to other primary therapies received (e.g. breast conserving surgery without radiation therapy). Second, we considered the specific

components of primary tumor therapy (axillary dissection, definitive surgery [mastectomy vs. breast conserving surgery], and radiation therapy).

Analytic Strategy

We obtained descriptive statistics for all study variables. We then performed a series of bivariate analyses, examining the relationships between independent variables and the dependent variable, using independent samples t-tests and chi-square tests as appropriate. Next, we developed multiple logistic regression models whose independent variables included all the statistically significant associations ($p < 0.05$) found in bivariate analyses, as well as all breast cancer treatment variables. We used stepwise multiple logistic regression techniques with significance criterion of 0.1 for entry or removal from the model.

Results

Two hundred fifteen women (71%) from the original cohort were interviewed three to five months following their definitive surgery and served as the study sample for this analysis. Sample characteristics are similar to those of the full cohort (5). Almost two-thirds (59%) were ≥ 65 years of age. Most were white (95%) and had a high school education or greater (84%). Half were married; most of the remainder were widowed. The average BMI was 25.98 (± 5.05) and the average comorbidity score was 7.09 (range 3-20). Most patients had small tumors (77% ≤ 2 cm) and were node negative (80%). The majority (57%) had undergone breast conserving surgery with axillary dissection followed by radiation therapy; 23% had undergone modified radical mastectomy. Of the 43 who received other than these standard primary tumor therapies, 23 underwent breast conserving surgery followed by radiation but without axillary dissection; 12 underwent breast conserving surgery and axillary dissection but did not receive radiation therapy; five underwent breast conserving surgery but neither axillary dissection nor radiation therapy; and the remainder either underwent simple mastectomy without radiation ($n=2$) or underwent biopsy or radiation therapy only ($n=2$). About a quarter of all subjects (27%) reported a decline in upper body function following their breast cancer treatment.

On bivariate analysis (Table 1), women who reported a decline in upper body function since breast cancer treatment had higher BMIs and cardiopulmonary comorbidity scores than those who did not report worsened upper body function, although only the comorbidity difference was statistically significant. In addition, women who received other than standard primary tumor therapies were about half as likely to report worsened upper body function as those who received either breast conserving surgery with axillary dissection and radiation therapy or a modified radical mastectomy (16% vs. 28% and 32%, $p = 0.18$). With respect to the

individual components of primary tumor therapy, women who underwent axillary dissection, mastectomy, or radiation therapy were all somewhat more likely to report a decline in upper body function since treatment than those who did not, but none of these relationships reached statistical significance.

In a multiple logistic regression model that included standard therapies (modified radical mastectomy and breast conserving surgery with axillary dissection followed by radiation therapy), with non-standard primary tumor therapies as the referent group (Table 2, Model 1), women who received breast conserving surgery with axillary dissection and follow-up radiation therapy were 2.2 times more likely to report a decline in upper body function ($p=0.09$), and women who received modified radical mastectomy were 2.8 times more likely to experience a decline in upper body function ($p=0.05$). Cardiopulmonary comorbidity was also an independent predictor of a decline in upper body function ($p=0.02$). In a second multiple logistic regression model (Table 2, Model 2), women undergoing mastectomy or radiation therapy were each more than six times more likely to report a decline in upper body function than those who did not ($p=0.02$). As in Model 1, cardiopulmonary comorbidity also was an independent predictor of a decline in upper body function following breast cancer treatment ($p=0.04$).

Discussion

We have found that among older women with early stage breast cancer, the extent of primary tumor therapy, as well as specific components of therapy, and self-reported cardiopulmonary comorbidity are risk factors for a decline in upper body function during the early months following primary breast cancer therapy. To our knowledge, this is the first study to evaluate the both the early effects of different treatment regimens as well as comorbidity in a group of older women with early stage breast cancer.

Sneeuw and colleagues examined late functional outcomes (an average of four years after treatment) among women of various ages who received breast conserving surgery, axillary dissection, and radiation therapy. In this study from the Netherlands of 76 women (age range 37-75) who were treated between 1975 and 1985, nearly half of the subjects reported a little (34%) or moderate (13%) limitation of movement in the arm and shoulder on the treatment side (9). Gerber and colleagues compared functional outcomes among participants in a randomized clinical trial who received either modified radical mastectomy or breast conserving surgery with axillary dissection and follow-up radiation therapy. All subjects also participated in an extensive structured rehabilitation program. The average number of days to reach functional range of motion did not differ between the groups, but twice as many women who were treated in the breast conserving surgery treatment group reported chest wall tenderness one year after treatment, as compared to the women in the modified radical mastectomy treatment arm (58.4% vs. 27.4%, $p < 0.0001$) (10). These data suggest that breast conserving surgery in conjunction with axillary dissection and radiation therapy may have substantial late functional consequences.

Our data are consistent with these investigations and extend those of Satariano and colleagues (3, 4). They demonstrate that there are early functional consequences among older

women who receive either modified radical mastectomy or breast conserving surgery with axillary dissection followed by radiation therapy, although the risk associated with modified radical mastectomy is greater. Furthermore, our treatment component-specific analyses suggest that radiation therapy contributes to the increased risk of functional decline among women who undergo breast conserving surgery, in keeping with the findings of Gerber and colleagues (10). In our data, axillary dissection does not appear to have an independent influence, once the effects of type of surgery and radiation are taken into account. This may be because our measure of upper body function was insensitive to the difficulties experienced by women who undergo axillary dissection, or because the number of women who did not receive axillary dissection was relatively small. Fortunately, the advent of lymphatic mapping and sentinel lymph node biopsy is likely to decrease substantially the need for axillary dissection in the not distant future (11).

Finally, cardiopulmonary comorbidity burden also is a risk factor for a decline in upper body function following primary tumor therapy. Tasks that require upper body strength stress the cardiopulmonary system. Thus, cardiopulmonary disease burden may limit rehabilitation efforts during the early treatment recovery period.

Of interest, the group of women at least risk for a decline in upper body function were those who received less than standard primary tumor therapy. It is therefore important to consider whether the offering of less intensive treatment may preserve upper body function at the expense of longer term survival. A recent study by Goodwin and colleagues has documented that older women who receive less than standard breast cancer therapy are at greater risk of dying from their breast cancer than those who receive standard therapy (12). Furthermore, recent breast cancer mortality trends document that breast cancer mortality has decreased in all age groups except the oldest old, who are also at greatest risk for receiving less than standard treatment (2).

For many older women, the better short-term functional status associated with less intensive treatment may not offset the increased risk of breast cancer mortality.

Our findings must be considered with the study's major limitations in mind. First, we did not measure directly upper body function, either before or after treatment. Second, we did not gather side-specific information, either in relation to handedness or the side on which treatments were performed. Third, we did not collect information about prior recreational or occupational injuries involving the upper extremities. Fourth, our sample was relatively small and the confidence intervals around our estimates of risk are wide. Nonetheless, our data are consistent with the limited number of studies to date and make clinical sense. Whether the early impairments that we have observed will persist awaits the collection of follow-up data.

Given the critical importance of upper body function in maintaining independent living (13), our findings suggest that clinicians should consider the functional consequences of treatment when discussing treatment options and post-operative care with older women who have early stage breast cancer. For example, women who have cardiopulmonary comorbidity, regardless of the primary therapy that they chose, are likely to benefit from a supervised rehabilitation program. In addition, women who undergo both modified radical mastectomy and radiation therapy may be another group most likely to benefit from such a program. Finally, we need to design studies to find the best balance between treatment efficacy and functional morbidity for this group of patients.

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Table 1. Bivariate Relationships between Patient Characteristics and Decline in Upper Body Function (n=215)

Characteristic	Declined (n=57)	Not Declined (n=127)	P Value
<u>Demographic Characteristics</u>			
<u>Age (n , %)</u>			
55-64	26 (30)	62 (70)	0.74
65-74	21 (25)	64 (75)	
75 +	10 (25)	30 (75)	
<u>Education (n , %)</u>			
< High School	10 (29)	25 (71)	0.81
≥ High School	47 (27)	130 (73)	
<u>General Health Status (mean score)</u>			
Body Mass Index (BMI)	26.93	25.63	0.15
Comorbidity	7.76	6.87	0.05
<u>Breast Cancer Characteristics</u>			
<u>Tumor Size (n , %)</u>			
≤ 1 cm	15 (25)	46 (75)	0.64
> 1 - 2 cm	23 (25)	69 (75)	
> 2 cm	15 (32)	32 (68)	
<u>Node Status (n , %)</u>			
Negative	44 (25)	127 (75)	0.71
Positive	12 (29)	30 (71)	
<u>Breast Cancer Treatments</u>			
<u>Primary Tumor Therapy (n , %)</u>			
Modified Radical Mastectomy	16 (32)	34 (68)	0.18
Breast Conserving Surgery/ Axillary Dissection/Radiation Therapy	34 (28)	87 (72)	
Other	7 (16)	36 (84)	
<u>Specific Treatment Modalities (n , %)</u>			
<u>Axillary Dissection</u>			
Yes	50 (27)	133 (73)	0.39
No	6 (20)	24 (80)	
<u>Mastectomy</u>			
Yes	16 (31)	36 (69)	0.42
No	40 (25)	120 (75)	
<u>Radiation Therapy</u>			
Yes	43 (29)	105 (71)	0.22
No	14 (21)	52 (79)	

Table 2. Multiple Logistic Regression Models Predicting A Decline in Upper Body Function in Relation to Breast Cancer Treatment

Characteristic	β Coefficient	Odds Ratio (95% CI)	
<u>Model 1</u>			
Primary Tumor Therapy			
Other (referent)	-----	----	
Breast Conserving Surgery	0.7678	2.2	(0.875, 5.53)
Modified Radical Mastectomy	1.0305	2.8	(1.002, 7.84)
Cardiopulmonary Comorbidity	0.1393	1.15	(1.03, 1.29)
<u>Model 2</u>			
Mastectomy	1.9251	6.86	(1.41, 33.44)
Radiation Therapy	1.8848	6.59	(1.35, 32.16)
Cardiopulmonary Comorbidity	0.1185	1.13	(1.01, 1.26)

Title: Comparison of interview-based and medical record-based indices of comorbidity among breast cancer patients

Short Title: Comorbidity from interview or record

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ABSTRACT

Objectives: To compare patient interview-based and medical record-based measures of comorbidity and their relation to primary tumor therapy, all cause mortality, self-reported upper body function, and overall physical function.

Methods: 303 breast cancer patients age 55 years or older and diagnosed at 1 of 5 Boston hospitals were enrolled. Patient interviews and medical record abstracts provided the information necessary to construct the Charlson index, Satariano index, and a new interview-based index of cardiopulmonary comorbidity. These indices were used alone and in combination to predict the patient outcomes.

Results: The indices of comorbidity corresponded well with one another. No index of comorbidity predicted mortality or receipt of definitive primary therapy. The new interview-based index of cardiopulmonary comorbidity was a better predictor of upper body function and overall physical function than the interview-based or medical record-based Charlson or Satariano indices of comorbidity.

Conclusion: Older breast cancer patients are able to provide information about their diseases and related symptoms that correlates well with medical record-based measures of comorbidity and displays similar patterns of predictive power. A new self-reported measure of cardiopulmonary comorbidity performs better than the medical record-based measures for predicting patient-related functional outcomes.

INTRODUCTION

Interest in explaining and reducing sources of variation in medical care has burgeoned, fueled by increasing concerns about the costs, quality, and outcomes of care. Critical to the discourse is the accurate measurement of comorbidity. For example, studies conducted throughout the world over the past decade have documented that breast cancer care for women ≥ 65 years differs substantially from that of younger postmenopausal women, with differences being most pronounced between those ≥ 75 years and their younger counterparts (1–11). Because the questions of interest have been the relationships between age and appropriate breast cancer therapy, as well as between age and mortality, statistical adjustment for comorbidity has been critical. The most popular methods of comorbidity measurement derive from medical record- or claims-based counts of medical conditions, with or without weighting for severity. With appropriate treatment as the outcome, comorbidity has failed repeatedly to completely explain age-associated variations in treatment (3, 6, 8, 10, 11). Furthermore, comorbidity has been found to vary in its relationship to survival (6, 12–14).

Interest in quality of life outcomes (15) as well as the recognition that older women represent the largest group of breast cancer survivors (16) have provided new reasons for the accurate measurement of comorbidity in older women. Such measurement can help disentangle the effects of breast cancer treatment from those related to underlying diseases. Although the medical record and claims-based approaches have their strengths, they also have important limitations. Medical record review is costly and concerns about patient confidentiality are beginning to limit investigators' access to medical records. Furthermore, medical records may incompletely capture patient symptoms and this is certainly the case when relying on claims data. Although the claims-based approach is less expensive than medical record review, the rapid

migration of older persons into managed care plans which do not submit claims to Medicare increasingly limits its applicability. Finally, claims information is generally insufficient to answer important questions about patterns of care, particularly in relation to treatments not covered by Medicare (e.g. tamoxifen) and health outcomes other than mortality.

Because of these limitations, we and others have begun to evaluate the use of interview-based reports of comorbidity (11, 17–20). Studies comparing interview-based versus medical record-based information are promising. In this paper we compare interview-based and medical-record-based measures of comorbidity and their relation to a range of patient outcomes, including primary tumor therapy and all cause mortality, as well as self-reported upper body and overall physical function.

METHODS

Sampling

Details of the study have been described elsewhere (11). We studied women ≥ 55 years of age with newly diagnosed stage I and stage II invasive breast carcinoma who were cared for at one of five hospitals in Boston, Massachusetts. Women were ineligible if they had a history of another cancer diagnosis within the previous five years or had any prior history of breast cancer. Study participants were sent an introductory letter signed by their surgeon and a consent form at approximately two to three months following definitive surgical treatment. An interviewer further explained the study, answered questions, and obtained informed consent.

Data Collection

Data were collected from patients' medical records and through a 35 minute computer-assisted telephone interview with consenting eligible patients. Data collected from medical records included: tumor size, axillary node status, breast surgery or surgeries performed (mastectomy or breast conserving surgery, with or without axillary dissection), receipt of post-operative radiation therapy, and whether the patient had any of a series of specified co-existing conditions: hypertension, congestive heart failure, angina, previous myocardial infarction, emphysema, chronic bronchitis, asthma, stroke, dementia, Parkinson's disease, diabetes mellitus, and thyroid disease. Co-existing conditions other than those specified were also recorded. The patient telephone interview ascertained demographic variables, the SF-36 Health Survey (21), diagnoses made by a physician of the same specified co-existing conditions collected from the medical records, and symptoms of cardiopulmonary diseases.

Major Analytic Variables

Dependent Variables. Our first dependent variable was a dichotomous variable representing whether or not women received definitive primary tumor therapy for their breast cancer. We defined definitive therapy as modified radical mastectomy or breast conserving surgery with axillary dissection and radiation therapy.

Our second dependent variable was the time to death from any cause. For this preliminary analysis, we ascertained deaths among the population by matching the identification of patients who had been lost to interview follow-up against the state's death records.

For our quality of life outcomes we considered both a breast cancer-specific as well as a general measure of physical function. Our breast cancer-specific measure was a dichotomous variable representing decline in upper body function in relation to breast cancer treatment. Patients were classified as having a decline in upper body function in relation to their breast cancer treatment if: 1) they reported having no difficulty in performing any of three tasks requiring upper body function prior to treatment, and reported that any of these tasks were somewhat difficult, very difficult, or that they did not do the task in the four weeks prior to interview, 2) they reported that performing any of the three tasks requiring upper body function was somewhat difficult prior to treatment, and reported that the same tasks were very difficult or that they did not do the tasks, in the four weeks prior to interview, or 3) they reported that performing any of the three tasks was very difficult prior to treatment, and that they did not do the same tasks in the four weeks prior to interview. Patients who did not meet any of these classifications were categorized as having no treatment-related decline in upper body function.

Our measure of general function was the continuous physical function index (PFI10) from the SF-36 Health Survey (21), which was administered to these patients at their baseline interview.

Independent Variables. We constructed five different measures of comorbidity. The first was a self-reported measure of cardiopulmonary comorbidity derived from the Total Illness Burden Index (17). The larger Total Illness Burden Index includes measures of 15 different disease categories. We chose to assess the subset of cardiopulmonary items because we thought that from a clinical perspective they were most likely to be related to the outcomes of interest. To derive the cardiopulmonary comorbidity score, individual scores are assigned to ischemic heart disease, chronic obstructive pulmonary disease, and congestive heart failure (Figure 1).

Second, we constructed the Satariano index of comorbidity (12) from the medical record abstract and from the subject's interview. This index includes as comorbid conditions myocardial infarction, other types of heart disease (valvular disease, arrhythmia, and congestive heart failure), diabetes mellitus, other forms of cancer, and respiratory, liver, and gallbladder conditions. The score was then collapsed into categories of 0, 1, 2, or 3+ conditions as described by the developers of the index (12). Dummy variables representing each non-zero category were included in the multivariate regression models. Our medical record-based Satariano index differed from the original index only in that we did not record histories of other cancers (12). Women were ineligible for our study if they had a history of another cancer within five years of the breast cancer diagnosis and were ineligible if they had any history of another breast cancer. Our patient interview-based Satariano index did not include diagnoses of gall bladder disease or liver disease because the interview did not ask about these conditions. By medical record review, 27 patients had gall bladder disease and four patients had liver disease.

Third, we constructed the Charlson index of comorbidity (13) from the medical record information and from the subject's interview. This index includes as comorbid conditions myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, liver disease, diabetes mellitus, malignancies, and AIDS. Weights are given to conditions with greater severity (e.g. diabetes mellitus with end organ damage receives a weight of 2 and moderate or severe liver disease receives a weight of 3). In this scoring scheme, weighted scores were then categorized as 0, 1-2, 3-4, or 5+ as described by the developers of the index (13). Dummy variables representing each non-zero category were included in the multivariate regression models. Our medical record-based Charlson index differed from the original index in that we could not include the higher order conditions weighted most heavily by Charlson because we did not collect these measures of severity. Given the nature of the higher order conditions and of the study population, we expect that our approximation would differ little from the Charlson comorbidity index for most subjects. Our subject interview-based Charlson index also did not include dementia, peptic ulcer disease, or liver disease because the interview did not ask about these conditions. By medical record review, one patient had dementia, four patients had peptic ulcer disease, and four patients had liver disease.

Potential Confounding Variables. We included the following potential confounding variables in our multivariate models as appropriate: age; education (< high school versus $\geq$ high school); living arrangement (living alone versus living with one or more household members); marital status (married or living with someone versus any other); body mass index (BMI, self-reported weight in kilograms divided by height in meters squared); tumor stage (stage I versus stage II); primary breast cancer therapy (mastectomy versus breast conserving surgery and

radiation therapy); axillary node evaluation (performed or not); and days to baseline interview from date of definitive surgery.

Analytic Strategy

To assess the correspondence between the measures of comorbidity, we calculated the correlation between all possible pair-wise combinations of the five measures of comorbidity. For this analysis only, the Charlson and Satariano indices were included as continuous measures.

For each dependent variable, we constructed a multivariate model that included the appropriate confounding variables. For the dichotomous variables, we used logistic regression as the multivariate technique. For the continuous dependent variable, we used linear regression as the multivariate technique. For the survival analysis, we used proportional hazards regression as the multivariate technique. After including the confounding variables, we first added the cardiopulmonary comorbidity variable. We then added the cardiopulmonary comorbidity variable in combination with the Satariano and Charlson dummy variables. We determined whether the cardiopulmonary comorbidity variable adequately predicted the dependent variables by calculating the p-value associated with the improvement in model fit engendered by adding the Satariano or Charlson variables. When the addition of the Satariano or Charlson variables significantly improved the model fit, we compared the standardized coefficients of the cardiopulmonary comorbidity score and an ordinal variable representing the Satariano or Charlson index. We conducted the analysis first with the Charlson and Satariano indices derived from the medical record and then repeated the analysis with these indices derived from the subject interviews.

RESULTS

We enrolled 303 patients during the study period (Table 1). Most of the women (83%) had at least a high school education. Two-thirds of the women had stage I breast cancer, the rest had stage II disease. The majority of the women (64%) received breast conserving surgery and radiation therapy for their primary treatment and 85% had an axillary node dissection. Three-quarters of the cases met our standards for definitive primary tumor therapy. Most (75%) of the baseline interviews occurred between 100 and 160 days after the patient's definitive surgery.

About one-third of the patients suffered some decline in upper body function by the date of their interview. Seventeen percent scored below 50 — on a scale from 0 to 100 — on the SF-36 Health Survey index of physical function. We located death certificates for 18 of the 24 patients reportedly lost to follow-up due to death. Thirteen of these 18 deaths were attributed to the patient's breast cancer on the death certificate.

The average of the interview-based comorbidity score increased regularly as the Charlson and Satariano indices increased (Table 2), indicating good correspondence on average between these three methods of rating the patient's comorbid disease status. The correspondence held whether the Charlson and Satariano indices were derived from medical records or from subject interviews. The pair-wise correlations between the continuous measures of each comorbidity index further demonstrates the correspondence (Table 3). The correlation coefficient of the cardiopulmonary comorbidity index with the medical record Charlson index was 0.45 ($p \leq 0.001$), with the medical record Satariano index was 0.52 ($p \leq 0.001$), with the patient interview Charlson index was 0.75 ($p \leq 0.001$), and with the patient interview Satariano index was 0.73 ($p \leq 0.001$).

Table 4 shows the predictive power of the cardiopulmonary comorbidity measure for each of the dependent variables. In addition, it shows the p-value associated with the improvement in model fit contributed by the Charlson or Satariano comorbidity index in combination with the cardiopulmonary comorbidity measure.

The cardiopulmonary measure of comorbidity did not predict receipt of definitive therapy. Furthermore, none of the other four measures of comorbidity added significant predictive power to the model.

None of the measures of comorbidity predict mortality, perhaps because of the short follow-up time and our inability to segregate decedents by cause of death. Further follow-up will likely yield sufficient numbers of decedents to allow a more thorough examination of these relations.

The interview-based cardiopulmonary comorbidity measure did predict upper body dysfunction. None of the other four measures of comorbidity added significant predictive power to the model after the cardiopulmonary comorbidity score was included.

Finally, the interview-based cardiopulmonary comorbidity measure strongly predicted the physical function subscale of the SF36 when entered in the multivariate models. The negative coefficients shown in Table 4 for the physical function index indicate that increasing cardiopulmonary comorbidity is associated with declining physical function. All comorbidity measures except the medical-record derived Satariano index significantly improved the model fit when added to the multivariate model that included the cardiopulmonary comorbidity score. This observation suggests that the cardiopulmonary comorbidity index did not fully explain the relation between increasing comorbidity and declining function. In each model, though, the standardized coefficient of the cardiopulmonary comorbidity score indicated that it was a more

powerful predictor than the Charlson or Satariano indices, whether they derived from the medical record or from the patient interview (data now shown). Therefore, if one could choose only a single measure of comorbidity to predict physical function, the cardiopulmonary comorbidity index would be preferred — at least in this population.

DISCUSSION

In this comparison of various methods and sources of comorbidity measurement we found that, regardless of the method or source, no measure of comorbidity was statistically significantly associated with the receipt of definitive primary tumor therapy. In other studies the observed relationship between comorbidity and primary tumor therapy has varied. Although Greenfield and colleagues found that comorbidity and age were independently and significantly associated with definitive treatment among women 50 years or older (3), Bergman found that advanced age (≥ 75 years) was a better predictor of treatment than was comorbidity (6). Both studies relied on medical record-based measures of comorbidity. Similarly, in studies using claims-based Charlson indices, Newschaffer et al. found that comorbidity had no relationship to surgical or radiation therapy (10), whereas Ballard-Barbash found modest relationships between comorbidity and both surgical and radiation therapies after controlling other potentially confounding factors (8). In both the Newschaffer and Ballard-Barbash studies, patients in the oldest age groups were less likely to receive these therapies, independent of all other measured variables (8,10).

Although not central to this investigation, our findings and those of others lead us to conclude that considerations of comorbidity do not completely drive therapeutic decisions regarding primary tumor therapy and do not explain the relationship between age and treatment patterns, regardless of the method of comorbidity measurement. Nonetheless, adequate measurement of comorbidity should be required of all studies of age-associated variations in breast cancer care. Here adequacy of measurement should be defined in terms of the risks and benefits of therapy. Thus, a measure of cardiopulmonary comorbidity may well be adequate for

studies of surgical and/or radiation therapy. However, studies of adjuvant chemotherapy would need to include laboratory measures of renal and hepatic function.

Although attention to the measurement of comorbidity is important in studies of age-associated variations in breast cancer care, equal attention should be given to alternative explanations. For example, patient's functional status is likely to be important, because comorbidity and functional status are known to contribute unique information to our understanding of the health status of older persons (22–24). However, studies that have controlled for functional status, either based on medical record information (3) or patient's self-report (11) have found that age persists as an independent predictor of treatment. The lack of association may reflect the need for more detailed measures of functional status and further studies are needed that measure functional status more comprehensively. Additional studies are also needed to more adequately explore the roles of physician attitudes and fully informed patient preferences as predictors of treatment.

With respect to mortality, none of our comorbidity measures was associated. This may be because the number of deaths in our sample is, as yet, small. Newschaffer and colleagues recently compared Medicare claims versions of the Charlson and Satiriano indices with their medical record-based versions in a sample of women aged 67 or older newly diagnosed with breast cancer. Although the claims-based and medical record-based methods had poor agreement, indices derived from both sources were modestly (odds ratios of 1.28 to 1.53) associated with three to five year all cause mortality, controlling for age, stage, and treatment. The Charlson approach performed somewhat better than the Satiriano approach, with the Charlson claims-based score adding modest prediction over and above the Charlson medical record-based score (6).

Finally, we found that patient self-report of cardiopulmonary comorbidity was a better predictor of breast cancer-specific as well as general physical function than were either the medical record- or patient interview-based Satariano and Charlson indices. The fact that neither the medical record- nor patient interview-based Satariano and Charlson measures performed as well suggests that the observed relationships are not due to measurement source (*i.e.* medical record *vs.* patient). When symptoms reflect disease severity, patients may be a better source of information than their physicians. Indeed, in comparison with patients' report of cardiopulmonary comorbidity, both the Satariano and Charlson, regardless of source, underestimated comorbidity 32-34% of the time. This may in part be because neither method takes into account the contribution of symptoms. For example, in the Charlson index, severe pulmonary and cardiac disease receive the same weighting as do mild forms of these diseases (13).

Studies comparing medical records and patient self-report suggest that patients are most accurate when asked about well-defined conditions such as heart disease or diabetes mellitus and least accurate for less well-defined conditions such as arthritis (17,18). Older age and less education have been variably associated with lower agreement between medical records and self-report (18–20). Thus, studies in which well-defined diseases are critical and/or in which patient symptoms are relevant, patient self-reports of diseases and symptoms may be sufficient, if not superior, for the measurement of comorbidity. This approach may be particularly useful in circumstances where missing data in medical records are common.

Although our findings are promising, they must be viewed with the following limitations in mind. First, the women in our study were mostly white and well-educated. Nonetheless, they ranged in age up to 97, so included women at greatest risk for a large burden of comorbid

conditions. Second, we did not construct our data collection instruments to fully represent the Satariano and Charlson indices. Thus, some of the underestimation of these measures may be related to incomplete data collection. The medical record-based Charlson index consistently underestimated diagnoses identified by a complete ascertainment through patient interview in a similar study (20). The interview-based Charlson and Satariano indices may therefore balance the incomplete assessment of diseases with a more complete ascertainment of the diseases that were assessed. Third, our sample size was relatively small and resulted in imprecise estimates of effect. Fourth, the small number of deaths preclude definitive statements about the relationship between our various comorbidity measures and all cause mortality.

Nonetheless, we believe that our data support the following conclusions. First, older breast cancer patients are able to provide information about their diseases and related symptoms that correlates well with medical record-based measures and displays similar patterns of predictive power. Second, our self-reported measure of cardiopulmonary comorbidity performs better than our medical record-based measures for predicting patient-related functional outcomes. Continued refinement of this approach offers promise for the efficient and valid measurement of comorbidity.

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Figure 1: Derivation of the cardiopulmonary comorbidity score from patient interview responses.

ISCHEMIC HEART
DISEASE

+

CHRONIC
OBSTRUCTIVE
PULMONARY
DISEASE

+

CONGESTIVE
HEART FAILURE

no heart attack or
angina - 0

heart attack or
angina - 2

heart attack and
angina - 4

no emphysema,
chronic bronchitis,
or asthma - 0

diagnosis of
emphysema,
chronic bronchitis,
or asthma - 4

no diagnosis of
CHF and no leg
swelling - 0

no diagnosis of
CHF and any leg
swelling - 2

diagnosed CHF - 4

+1 if:

(1) shortness of breath
more than a little of the time
while resting, or
(2) shortness of breath
more than a little of the time
when walking less than one
block, or
(3) shortness of breath
more than some of the time
when climbing one flight of
stairs

-1 if:

(1) no shortness of breath
when lying down flat, and
(2) a little or no shortness of
breath when sitting, resting
or when walking less than
one block, and
(3) some, little, or no
shortness of breath when
climbing one or several
flights of stairs, and
(4) no chest pain or
pressure when exercising

or +1 if:

(4) chest pain or pressure
almost every week or more
when exercising

Table 1: Distributions of patient characteristics

Characteristic	Number	Percent
Age at diagnosis		
55-64	126	41.6
65-74	111	36.6
75+	66	21.8
Education		
< 12 years	51	17.0
>= 12 years	249	83.0
Living Arrangement		
alone	197	65.7
with 1 or more	103	34.3
Marital Status		
married or living with someone	153	50.8
all other	148	49.2
Body Mass Index (kg/m2)		
<= 23	91	30.5
>23 to <=27.5	120	40.3
>27.5	87	29.2
Breast Cancer Stage		
Stage I	193	63.9
Stage II	109	36.1

Axillary Node Dissection

Yes	258	85.4
No	44	14.6

Primary Tumor Therapy

Breast Conserving Surgery and Radiation Therapy	195	64.3
Mastectomy	71	23.4
Other	37	12.2

Radiation Therapy

Yes	206	68.0
No	97	32.0

Appropriate Therapy

Yes	234	77.2
No	69	22.8

Days between Definitive Surgery and Interview

1-100	28	9.2
101-130	138	45.5
131-160	74	24.4
>161	63	20.8

Upper body Function Decline

Yes	106	35.6
No	192	64.4

Physical Function Index (scaled 0 to 100)

0-25	13	4.4
26-50	37	12.4
51-75	86	28.4
76-100	162	53.5

Vital Status

Died from Breast Cancer	13	4.3
Died from other than Breast Cancer	5	1.7
Death certificate not located	6	2.0
Alive	279	92.1

Table 2: Relationships between the Charlson and Satariano indices and interview-based index of cardiopulmonary comorbidity (CC)

CC		CC	Range of CC	Number of Subjects
Mean $\pm$ SD		Standard Error of Mean		
Satariano Index Group				
Medical Record Derived				
Zero	0.74 $\pm$ 1.44	0.10	0-8	205
One	2.21 $\pm$ 2.80	0.32	0-13	77
Two	4.89 $\pm$ 3.31	0.78	0-10	18
Three or more	10.00 $\pm$ 8.66	5.00	0-15	3
Satariano Index Group				
Patient Interview				
Derived				
Zero	0.49 $\pm$ 1.04	0.07	0-6	225
One	3.37 $\pm$ 2.64	0.34	0-10	59
Two	6.44 $\pm$ 3.68	0.87	1-15	18
Three or more	15		15	1

Charlson Index Group				
Medical Record Derived				
Zero	0.91 ± 1.80	0.12	0-13	237
One or two	3.08 ± 3.04	0.39	0-11	62
Three or four	8.50 ± 7.68	3.84	0-15	4
Five or more				0
Charlson Index Group				
Patient Interview				
Derived				
Zero	0.38 ± 0.81	0.06	0-5	214
One or two	3.61 ± 2.70	0.29	0-11	85
Three or four	12 ± 3.61	2.08	8-15	3
Five or more	15		15	1

Table 3: Correlation coefficient (p-value) between pair-wise combinations of the continuous indices of comorbidity

	Cardiopulmonary		Medical Record		Patient Interview	
	Comorbidity	Charlson	Charlson	Satariano	Charlson	Satariano
Cardiopulmonary	1.0	0.45	0.52	0.75	0.73	
comorbidity	—	(≤ 0.001)	(≤ 0.001)	(≤ 0.001)	(≤ 0.001)	
Medical Record		1.0	0.68	0.58	0.58	
Charlson		—	(≤ 0.001)	(≤ 0.001)	(≤ 0.001)	
Medical Record			1.0	0.55	0.60	
Satariano			—	(≤ 0.001)	(≤ 0.001)	
Patient Interview				1.0	0.87	
Charlson				—	(≤ 0.001)	
Patient Interview					1.0	
Satariano					—	

Table 4: Relationships between the dependent variables and the index of cardiopulmonary comorbidity, controlling for the Charlson or Satariano index of comorbidity.

Dependent Variable	Model	Relative risk associated with a unit increase in cardiopulmonary comorbidity (95% CI)	p-value associated with addition of Charlson or Satariano index
Appropriate primary tumor therapy	CC* alone	1.03 (0.91, 1.16)	not applicable
	CC+MR† Charlson	0.97 (0.85, 1.11)	0.10
	CC+MR Satariano	1.02 (0.88, 1.17)	0.94
	CC+PI‡ Charlson	0.98 (0.81, 1.19)	0.24
	CC+PI Satariano	0.93 (0.78, 1.12)	0.39

All cause mortality	CC alone	0.84 (0.65, 1.09)	not applicable
	CC+MR Charlson	0.84 (0.64, 1.11)	0.95
	CC+MR Satariano	0.85 (0.64, 1.12)	0.98
	CC+PI Charlson	0.84 (0.60, 1.17)	0.99
	CC+PI Satariano	0.89 (0.64, 1.24)	0.78
Upper body dysfunction	CC alone	1.16 (1.04, 1.30)	not applicable
	CC+MR Charlson	1.13 (0.99, 1.27)	0.18
	CC+MR Satariano	1.14 (1.00, 1.31)	0.34
	CC+PI Charlson	1.12 (0.95, 1.33)	0.39
	CC+PI Satariano	1.14 (0.97, 1.34)	0.20
Physical function index (PFI10)	CC alone	-2.56 (-3.43, -1.68)	not applicable
	CC+MR Charlson	-2.26 (-3.23, -1.30)	0.001
	CC+MR Satariano	-2.65 (-3.68, -1.62)	0.142
	CC+PI Charlson	-2.41 (-3.78, -1.04)	0.063
	CC+PI Satariano	-2.75 (-4.03, -1.48)	0.002

* CC = cardiopulmonary comorbidity index

† MR = derived from the patient's medical record

‡ PI = derived from the patient's interview

Quality of Care for Older Women with Breast Cancer: Is Surgeon Gender Important?

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Abstract

Context. - Over the past decade and a half a substantial literature has documented age-related variations in breast cancer care. Accumulating evidence suggests that these variations impact the health outcomes (breast cancer recurrence and mortality) of older women with breast cancer.

Surgeon gender may be an important source of age-related variations in care.

Objective. - To examine the relationship between surgeon gender and primary tumor therapy and systemic adjuvant therapy among 303 older women with early stage breast cancer cared for by 21 surgeons in Boston, Massachusetts.

Design. - Cross-sectional observational study.

Patients. - Women at least 55 years of age with newly diagnosed stage I or II breast cancer.

Main Outcome Measure. - Definitive primary tumor therapy and systemic adjuvant therapy.

Results. - Controlling for age and stage, patients of female surgeons were less likely to receive non-definitive treatment, with the strongest effect being observed for the receipt of neither definitive primary tumor therapy nor systemic adjuvant therapy (OR 0.24; 95% CI 0.1, 0.4).

Conclusion. - Women with early stage breast cancer cared for by female surgeons are more likely to receive standard therapies. Understanding the reasons for this could inform the design of effective interventions to improve the quality of breast cancer care for older women.

Introduction

Over the past decade and a half a substantial literature has documented age-related variations in breast cancer care. Although some aspects of care have changed over this period of time (e.g., breast conserving surgery has increased), age-related variations have persisted into the 1990's (1). The next level questions are 1) Do these variations make a difference with respect to important health outcomes – in other words, is this a quality of care issue? If so, 2) What can be done to effect a change?

Accumulating evidence suggests that the observed variations impact the health outcomes of older women with breast cancer. Specifically, studies from the United States and Italy have identified both higher recurrence rates and higher mortality rates among women who receive less than standard therapy (2-4). Furthermore, breast cancer-specific mortality rates are declining among women less than 70 years old, but are either stable (70-79 year olds) or increasing (80 + year olds) among those 70 years or older (5). Increasing rates of screening mammography and better treatment regimens may explain declining mortality rates among women less than 70 years old. Although screening mammography rates decline progressively with age (7), there is no evidence to suggest that the diagnosis of late stage disease among the oldest women has been increasing over time. This leaves the receipt of less than definitive treatment as the better explanation for why mortality rates among older women are increasing, particularly among those aged 80 years or older (7). This contention is supported by the available age-specific clinical trial data that fail to demonstrate that treatment efficacy is modified by age (6-8).

The quality of the medical encounter may be an important source of age-related variations in breast cancer care. Studies of physician-patient interactions have demonstrated that the quality of physician-patient interactions decreases with patient age. Physicians spend less time with

their older patients than they do with their younger patients (9, 10). Physicians also provide better information and support to their younger patients than to their older patients (11). These physician behaviors are compounded by the behaviors of older patients themselves. In general, older patients are less assertive and defer more to their physicians than do younger patients (12). Indeed, a recent study of over 1000 women with breast cancer found that 48% of women ≥ 70 years of age preferred to have a passive role in decision-making, compared with 36% of those 50-69 years, and 21% of those < 50 years of age (13).

Gender issues may accentuate the affects of these age-related behaviors. Because of gender disparities in life expectancy, most older patients are women. Until recently, most physicians were men. The latter circumstance is changing rapidly and a growing literature has documented differences among male and female physicians, both in their styles of interactions as well as in the care they deliver. For example, compared with male physicians, female physicians engage in more question-asking and information-giving (14). The longest visits are between female physicians and their female patients; the shortest visits are between male physicians and their female patients (14). Although several studies have documented that women are more likely to undergo cervical and breast cancer screening if they see female rather than male physicians (15-17), no study has documented that breast cancer care is similarly influenced.

As part of a study of age-related variations in breast cancer care (1), we examined the relation between surgeon gender and primary tumor therapy and systemic adjuvant therapy among older women with early stage breast cancer cared for by seven female surgeons and thirteen male surgeons in Boston, Massachusetts. We sought to determine whether surgeon gender was associated with primary tumor and systemic adjuvant therapy, once other relevant factors had been taken into account.

Methods

Data Collection

The study's methods have been described elsewhere (1). Participating women were at least 55 years old and newly diagnosed with stage I or II breast cancer. They could not have a history of breast cancer. The study was reviewed and approved by human subjects committees at the five participating institutions and written informed consent was obtained from study participants. Data were collected from women's medical records, a 35 minute computer-assisted telephone interview with consenting women, and the Massachusetts Physician Profiles database of the Board of Registration in Medicine of the Commonwealth of Massachusetts (18). Data collected from medical records included stage, estrogen receptor status, surgeries performed, and additional therapies received (radiation therapy, chemo- and/or hormonal therapy). Medical records were monitored for six months to determine whether radiation therapy and chemotherapy were initiated and completed or discontinued, and whether hormonal therapy was initiated. The patient telephone interview included questions about sociodemographic characteristics (age, marital status, and education); general health-related quality of life (as measured by the Medical Outcomes Study Short Form 36 (SF-36)) (19); the presence of physician-diagnosed cardiopulmonary diseases and the frequency of associated symptoms; and ratings of several aspects of physician-patient communication, including patients' perceptions of physician communication (a four item measure based on ratings of the quality of breast cancer information given to patients by their physicians, as well as physicians' abilities to give information, discuss treatment options, and tailor treatments to patient needs [Cronbach's $\alpha = 0.92$]); patients' ratings of their physicians' technical and interpersonal care (a four item measure of physicians' personal manner, communication skills, technical skills, and overall care [Cronbach's $\alpha = 0.95$]); and

patients' perceptions of their own abilities to communicate with their physicians (a three item measure based on patients' ratings of their abilities to get from, and to give information to their physicians [Cronbach's $\alpha = 0.96$]). We obtained training information about surgeons from the Massachusetts Physician Profiles database (18), including year graduated from medical school, fellowship training in surgical oncology, and board certification.

Major Analytic Variables: Our dependent variable has two components: 1) definitive primary tumor therapy, categorized as "yes" if the patient received either modified radical mastectomy or breast conserving surgery with axillary dissection followed by radiation therapy, otherwise "no"; and 2) systemic adjuvant therapy, categorized as "yes" if the patient received either chemotherapy or hormonal therapy alone, or in combination, otherwise "no". These two components were then combined to form a four level variable: no/no, no/yes, yes/no, and yes/yes.

For our independent variables we considered patients' demographic, health status, and tumor characteristics (stage (I/II) and estrogen receptor status (positive/negative)), and surgeons' gender (female/male). Patients' demographic characteristics included age (55-64, 65-74, and 75+), marital status (married/not married), and education (< high school/ $\geq$ high school). We measured comorbidity using patients' reports of diagnoses of chronic obstructive pulmonary disease, congestive heart failure, and ischemic heart disease, and related disease manifestations and symptoms that were part of the Total Illness Burden Index (20). We assessed physical function using the 10-item physical function subscale of the SF-36, which is scaled from 0-100 with a higher score indicating better function (19).

Statistical Analysis

We obtained descriptive statistics on all medical record and patient interview variables

and then examined the association between each of the independent variables and the outcome variable using analysis of variance and the chi-square test. Independent variables that were statistically significant ($p < 0.05$) at the bivariate level were entered into a polytomous logistic regression model, a generalization of the binary logistic regression model to more than two outcome categories (21). The model assumes that the categories are mutually exclusive. The odds ratio for a given independent variable (e.g., surgeon gender) at a given outcome level (e.g., no/no) represents the odds of receiving on/no over receiving yes/yes among patients cared for by male surgeons compared to those cared for by female surgeons (22). In choosing this analytic strategy we were concerned about violating the statistical assumption of independence. To address this concern we examined the correlation among patients within surgeon and the observed correlation coefficients were very small (e.g., 0.00, -0.03, 0.04) suggesting that the assumption of independence in the polytomous regression model is valid.

Finally, we performed a series of exploratory bivariate analyses. In these analyses we related surgeons' gender to patient characteristics as well as other surgeon characteristics, including number of years since medical school graduation and surgical oncology training.

Results

Study Sample

Three hundred three women participated in the study. A little more than half (58%) of our subjects were ≥ 65 years of age (range 55-97 years) and most were white (93%). About half were married (51%) and the majority had a high school education or more (83%). Their average comorbidity score was 7.06 (range 3-20). The majority of patients had stage I disease (64%). The majority of women in our study also underwent breast conserving surgery and axillary dissection followed by radiation therapy (56%); less than a quarter received a modified radical mastectomy (22%); the remaining 22% received other therapies. About two-thirds (67%) of the women studied also received some form of systemic adjuvant therapy. Of these, most (76%) received hormonal therapy alone. A much smaller percentage received either chemotherapy alone (13%) or both chemotherapy and hormonal therapy (11%).

Patient Characteristics and Therapies Received

Patient characteristics in relation to therapies received are displayed in Table 1. Older women were more likely to receive neither definitive primary therapy nor systemic adjuvant therapy (no/no) and less likely to receive both definitive primary therapy and systemic adjuvant therapy (yes/yes). A similar pattern was observed for women who were not married and those who had less than a high school education. There were no differences with respect to cardiopulmonary comorbidity, but patients with better physical function were more likely to receive definitive primary therapy, with or without systemic adjuvant therapy. As expected, patients with stage II disease were much more likely to receive both definitive primary therapy and systemic adjuvant therapy. However, there were no differences in relation to estrogen receptor status. Finally, women cared for by female physicians were more likely to receive both

definitive primary therapy and systemic adjuvant therapy, whereas women cared for by male physicians were more likely to receive neither.

Results of our polytomous regression model are displayed in Table 2. In each comparison with the referent group (definitive primary tumor therapy and systemic adjuvant therapy), older age and stage I disease were independently associated with each of the lesser treatment combinations. Controlling for these two characteristics, patients of female surgeons were less likely to receive each of the lesser treatment combinations, with the strongest effect being observed for the receipt of neither definitive primary tumor therapy nor systemic adjuvant therapy. Patients cared for by female surgeons were about one fourth as likely to receive neither therapy as compared to those cared for by male surgeons.

To further explore the physician gender finding, we examined patient characteristics in relation to surgeon gender (Table 3). Women seeing female versus male surgeons tended to be younger and better educated, although these differences were not statistically significant. Ratings of their abilities to communicate with their physicians were almost identical between groups. However, women cared for by female surgeons rated their physicians' communication skills and technical and interpersonal care more highly than did women cared for by male surgeons. In addition, women cared for by female surgeons were more likely to have had treatment options discussed with them by three or more breast cancer specialists than were women cared for by male surgeons (52% vs. 32%, $p=0.001$).

We also examined information obtained from the Massachusetts Physician Profiles database. The Profiles database provided information about 19 of the 20 surgeons. These surgeons, including seven women and 12 men, cared for 301 of the 303 patients. The seven female surgeons had trained somewhat more recently than the male surgeons (86% of female

surgeons had graduated from medical school within the past fifteen years as compared to 33% of the male surgeons, $p=0.06$). Females and males did not differ with respect to training in surgical oncology.

Discussion

In this study of breast cancer care received by older women, we found that surgeon gender was independently associated with the receipt of definitive primary tumor therapy and systemic adjuvant therapy, after statistical control for age and stage. Three important methodological questions must be addressed before considering the interpretation of this finding:

1) Are the findings due to one or two surgeon outliers, of either gender? 2) Is the observed relationship confounded by recency of training? Are patients of surgeons who are more recent medical school graduates more likely to receive more comprehensive treatment? And 3) Is the observed relationship an artifact of patient selection? To address the first question, we examined the distribution of treatments by surgeon. Not only were there no outliers, but the distributions of treatments were similar within female and male surgeon groups. To address the second question, we examined treatment patterns in relation to years since graduation from medical school. Treatment patterns did not vary as a function of years since medical school graduation. Furthermore, when we controlled for years since medical school graduation in a series of logistic regression models that included age, stage, and surgeon gender, the surgeon gender effect was strengthened, not weakened. Thus it does not appear as though patients of surgeons who are more recent medical school graduates are more likely to receive more comprehensive treatment.

With respect to the third question, the concern is that different kinds of women might seek care from female surgeons than seek care from male surgeons. Our data suggest that this is not the case. First, we found no significant differences with respect to patient age and education among women cared for by female and male surgeons (Table 3). Second, women seen by both groups of surgeons reported almost identical ratings of their abilities to communicate with their physicians. Third, in our polytomous logistic regression analysis, the effect of surgeon gender

persisted after statistical control for patient age and tumor stage. Taken together, these data do not support the argument that different kinds of women seek care from female surgeons than seek care from male surgeons. Although it is possible that unmeasured factors may be unbalanced across groups of women cared for by female as opposed to male surgeons, this seems unlikely.

In contrast to the above similarities, patients of female surgeons rated their surgeon's communication skills and technical and interpersonal care more highly than did patients of male surgeons. Moreover, patients of female surgeons were more likely to report discussing treatment options with three or more breast cancer specialists than patients of male surgeons.

Our findings are consistent with those of others who have explored gender differences in primary care settings (14, 23). These studies have documented that female physicians are more nurturing and expressive and have a stronger interpersonal orientation than do their male counterparts. In interactions with their female patients they contribute more equally to the interaction, allowing patients to tell their stories (23). This aspect may be particularly important for older women patients who are less likely than younger women to be assertive and to ask questions.

Although our findings are compelling, they deserve scrutiny. First, we need to consider whether the quality issue is over treatment by female surgeons or under treatment by male surgeons. This is an important question because studies of physician gender and patterns of cancer screening suggest that female physicians more be screening women for whom mammography is not indicated (e.g., women in their 30's) (16). To address this issue we categorized node-negative women as being at low, intermediate, and high risk of recurrence as defined by The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer (24), and node positive women as being at high risk of recurrence. We then

examined patterns of care in relation to risk of recurrence by surgeon gender. Among patients of female surgeons, 60% of those who received neither definitive primary tumor therapy nor adjuvant therapy were at low risk of recurrence. Among patients of male surgeons, 18% of those who received neither definitive primary tumor therapy nor adjuvant therapy were at low risk of recurrence. In contrast, no patients of female surgeons received neither therapy were classified as being at high risk of recurrence whereas 36% of patients of male surgeons who received neither therapy were so classified. These data support the assertion that most low risk patients are not being overtreated by female surgeons and that some high risk patients may be being undertreated by male surgeons.

However, the generalizability of our findings is limited by the characteristics of our study sample. Our older women with breast cancer were mostly middle-class white women from one city in the Northeast United States. Second, the surgeons who cared for them practiced in settings with academic affiliation. Third, the oldest women (75+) were underrepresented due to a higher refusal rate (1).

Nonetheless, the findings raise important questions related to the provision of quality care for older women with breast cancer. Surgeons provide the initial care for all women with breast cancer – both diagnostic as well as therapeutic care. Their discussions with women condition the broadening or narrowing of possible treatment options. Surgeons also facilitate referral to other breast cancer specialists – radiation and medical oncologists. Furthermore, they may be the ones who prescribe tamoxifen and monitor women for side effects and adherence, as well as for symptoms of recurrence. Thus, their role in breast cancer care is pivotal and has an enormous impact on the nature and quality of breast cancer care received.

If the quality of breast cancer care for older women is related to surgeon gender, what are

reasonable approaches to change? First and foremost, we need to better understand why this is the case. Only then can we design the most appropriate interventions designed to improve the care of older breast cancer patients. For example, although the development of interpersonal skills may come more easily to female physicians, all physicians are likely to benefit from interviewing skills training during medical school and beyond (25). However, unless physicians have more time to talk with and listen to their patients, these interventions are destined to fail. Thus, we need to think creatively about ways to help physicians provide information efficiently and effectively, be it by taking advantage of new technologies or by organizing some aspects of information-sharing with groups of patients (26). This is particularly important given the increasing time pressures placed on physicians who care for older patients, who often need more time to comfortably participate in their own health care decisions.

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TABLE 1. Patient Characteristics and Therapies Received*

Patient Characteristic	No/No (n=22)	No/Yes (n=46)	Yes/No (n=77)	Yes/Yes (n=157)	P-value
Demographics					
Age (years)					
55-64	5 (4%)	8 (6%)	35 (28%)	78 (62%)	0.001
65-74	8 (7)	10 (9)	28 (25)	65 (59)	
75+	9 (14)	29 (44)	14 (21)	14 (21)	
Marital Status					
Married	6 (4)	12 (8)	44 (30)	86 (58)	0.001
Unmarried	16 (10)	34 (22)	33 (22)	70 (46)	
Education					
< High school	10 (20)	11 (21)	10 (20)	20 (39)	0.001
≥ High school	12 (5)	34 (14)	67 (27)	136 (54)	
Health status					
Comorbidity	7.52	7.05	6.93	7.03	0.8
Physical function	66.90	65.81	76.17	75.19	0.03
Tumor characteristics					
Stage					
I	20 (10)	40 (21)	64 (33)	69 (36)	0.001
II	2 (2)	7 (6)	13 (12)	87 (80)	
Estrogen receptor status					
Positive	12 (6)	34 (16)	48 (23)	116 (55)	0.44
Negative	5 (8)	6 (9)	19 (28)	37 (55)	
Surgeon Gender					
Female	7 (4)	27 (16)	42 (24)	98 (56)	0.05
Male	15 (12)	20 (15)	35 (27)	59 (46)	

TABLE 1. Patient Characteristics and Therapies Received* (cont'd)

*No/No = No definitive primary tumor therapy
No systemic adjuvant therapy

No/Yes = No definitive primary tumor therapy
Systemic adjuvant therapy

Yes/No = Definitive primary tumor therapy
No systemic adjuvant therapy

Yes/Yes = Definitive primary tumor therapy
Systemic adjuvant therapy

TABLE 2. Polytomous Logistic Regression Predicting Receipt of Primary Tumor Therapy and Systemic Adjuvant Therapy*

	No/No	No/Yes	Yes/No
Patient Characteristic	OR (95% CI)	OR (95% CI)	OR (95% CI)
Age (years)			
55-64	—Referent—	—Referent—	—Referent—
65-74	7.84 (2.2, 27.4)	20.54 (7.2, 58.6)	3.34 (1.3, 8.7)
75+	12.42 (3.2, 48.0)	26.99 (9.2, 79.5)	2.82 (1.1, 7.2)
Stage			
I	18.59 (8.5, 40.5)	11.43 (6.9, 19.0)	7.38 (5.2, 10.5)
II	—Referent—	—Referent—	—Referent—
Surgeon Gender			
Female	0.24 (0.1, 0.4)	0.74 (0.5, 1.1)	0.59 (0.4, 0.8)
Male	—Referent—	—Referent—	—Referent—

*No/No = No definitive primary tumor therapy
No systemic adjuvant therapy

No/Yes = No definitive primary tumor therapy
Systemic adjuvant therapy

Yes/No = Definitive primary tumor therapy
No systemic adjuvant therapy

TABLE 3. Patient Characteristics and Surgeon Gender

Patient Characteristic	Surgeon Gender		P-value
	Female	Male	
Age (years)			
55-64	75 (60%)	51 (40%)	0.54
65-74	65 (59)	46 (41)	
75+	34 (52)	32 (48)	
Education			
< High school	26 (51)	25 (49)	0.31
≥ High school	146 (59)	103 (41)	
Own communication skills*	70.43	70.98	0.86
Physicians' communication skills*	95.93	89.16	0.001
Physicians' technical and interpersonal care*	97.52	93.30	0.01

*Analysis restricted to the 229 women who indicated that their surgeon was the doctor in charge of their breast cancer care.



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y)

23 Aug 01

MEMORANDUM FOR Administrator, Defense Technical Information
Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir,
VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to the technical reports listed at enclosure. Request the limited distribution statement for these reports be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by e-mail at judy.pawlus@det.amedd.army.mil.

FOR THE COMMANDER:

Encl


PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

Reports to be Downgraded to Unlimited Distribution

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