Sequelaes of Axillary Lymph Node Dissection in Older Women with Stage 1 and 2 Breast Carcinoma

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BACKGROUND. There are few data on the long-term sequelae of axillary dissection among older breast carcinoma patients. We describe the impact of axillary dissection in a cohort of older women.

METHODS. A longitudinal cohort of 571 patients with Stage 1 and 2 breast carcinoma, 67 years and older, diagnosed between 1995 and 1997 from 29 hospitals in five regions, and followed for 2 years. Data were collected from patients and medical charts. The primary outcome was posttreatment quality of life. Generalized estimation equation longitudinal modeling was used to evaluate the outcome, controlling for baseline function, comorbidity, age, clinical status, and other factors.

RESULTS. Sixty percent of women reported arm problems at some time in the 2 years after surgery. The cumulative risk of having arm problems 2 years posttreatment was three times higher (95% confidence interval 1.94–4.67) for women who underwent axillary surgery compared with women without axillary surgery, controlling for covariates. The effects of having axillary dissection and arthritis were multiplicative 2 years postsurgery. Arm problems were, in turn, the primary determinate of lower physical and mental functioning (P = 0.0001 and 0.04, respectively), controlling for other factors. Undergoing axillary dissection did not lessen fears about recurrence.

CONCLUSIONS. Arm problems after axillary dissection have a consistent negative impact on quality of life, suggesting that the risks may outweigh the potential benefits in this population. Cancer 2002;95:2445–54.

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KEYWORDS: axillary lymph node dissection, breast carcinoma, older women, arm problems.

Older women are the fastest growing segment of the U.S. population.1 Given the increase in breast carcinoma incidence with advancing age,2 older women are likely to account for an increasing absolute number of new breast carcinoma cases and survivors over the coming decades.3 These older breast carcinoma survivors represent a physiologically heterogenous group with multiple comorbid conditions.4–6 The interaction of breast carcinoma treatment and these chronic illnesses may impact cancer quality of life outcomes. One aspect of breast carcinoma treatment that may be particularly germaine to outcomes among older women is axillary lymph node dissection.

Operative staging information on the number of lymph nodes, if any, involved with metastatic disease has been the standard of care in evaluating the risk for recurrence and the need for adjuvant chemotherapy.7–9 Sentinel lymph node biopsy is an emerging technology...
that is being investigated as an alternative paradigm for evaluating lymph node status. Axillary lymph node dissection (with or without radiation) has been associated with short and intermediate-term morbidity in younger women, including lymphedema, arm pain, paresthesias, weakness, and impaired shoulder function. Currently, there are few data on the long-term sequelae of axillary lymph node dissection among older breast carcinoma patients. The goal of this study is to describe the impact of axillary lymph node dissection on several domains of symptoms and health-related quality of life in a cohort of older women followed for 2 years after surgery for Stage 1 and 2 breast carcinoma treated before the shift to surgical acceptance of sentinel lymph node biopsy. We hypothesized that women who had axillary lymph node dissection would have greater arm impairment than women who did not have axillary surgery, after considering the effects of age, preexistent comorbidity, functional status, and other factors. In addition, we hypothesized that axillary dissection would interact with other medical conditions, such as arthritis, in its effect on physical function domains. We also hypothesized that women who underwent axillary surgery would have less worry about recurrence and better mental function than those who did not, controlling for other treatments and stage.

MATERIALS AND METHODS
Setting and Population
The initial cohort was enrolled between November 1, 1995 and September 30, 1997. The details of the cohort recruitment have been described elsewhere. Briefly, women aged 67 years or older with newly diagnosed breast carcinoma from 29 hospitals in five geographic areas (Massachusetts, Texas, Washington, DC, upstate New York, and New York City) were recruited. An entry age of 67 years enabled women to have 2 years of Medicare claims so that we could estimate comorbid illnesses present before the diagnosis of breast carcinoma. There was no upper age limit for study eligibility. Women were eligible for participation if they had primary Stage 1, 2a, or 2b, disease histologically confirmed invasive breast carcinoma, and were able to complete the interview in English. Among the enrollees, surgeon permission was obtained to contact 84%. Of these women, 784 (67.7%) consented to participate and 66 were excluded post hoc due to recurrent disease or missing stage data. The remaining 718 women comprised the baseline population. Women were recontacted for follow-up interviews at 1 and 2 years postsurgery. Cumulatively, over the 2 years of follow-up, 4.5% were lost to follow-up, 3.8% died, and 3.8% were ineligible due to dementia. Among the remaining women, there was a 97.6% response rate to the first follow-up survey and a 92.7% for the second survey, leaving 571 women with complete data for the entire 2-year follow-up period (Fig. 1). The final sample was similar to women who were lost to follow-up, died, became ineligible, or refused in terms of stage at diagnosis, prevalence of preexisting arthritis, and baseline mental health (data not shown). However, compared with women included in the final sample, women who died or became ineligible had lower rates of axillary dissection (78.6% vs. 55.6% or 66.7%, respectively, \( P = 0.001 \)), less breast conservation and radiation (compared with other initial treatments), were older (74.6 vs. 78.7 or 79.2 years, respectively, \( P < 0.001 \)), had higher levels of prediagnosis comorbidity, and had lower physical function precancer diagnosis.

Data Collection
Baseline interviews were conducted approximately 3 months postsurgery. Women were contacted by trained staff 12 and 24 months postsurgical treatment for completion of a standardized 20–30-minute telephone follow-up interview. Data on surgical procedures, tumor stage, and comorbid medical conditions were recorded from charts at baseline.
Definition of Variables

Outcomes
We evaluated several domains of symptoms and health-related quality of life outcomes: difficulties with arm functioning, overall physical and mental functioning, holistic impact of breast carcinoma on women's lives, and worry about recurrence. Difficulties with arm functioning are defined as women having either swelling in the arm on the side of surgery, loss of arm movement on the side of surgery, or limitations in the full use of hands and fingers (yes/no).

Physical functioning domains (including impact of physical limitations on work or other usual activities, social relationships, and mental health) were measured using the physical components summary score from the Medical Outcomes Study—Short Form 12 (MOS SF12). Scores are normed to have a mean of 50 and a standard deduction of 10. Mental functioning was measured using the mental health components summary scale, which is scored in the same manner as the physical components summary. All scales had excellent reliability in our population (Cronbach’s alpha > 0.90, data not shown).

The holistic impact of breast carcinoma was assessed using responses to the single item, “Considering your overall health, how would you rate the impact of breast cancer on your life?” Fears of recurrence were measured using two items from the worry about cancer recurrence scale in the Cancer Rehabilitation Evaluation Survey—Short Form (CARES-SF) (“I worry about whether my treatments are working or have worked” and “I worry about whether the cancer is progressing or will come back”) and were rated very much to not at all (Cronbach’s alpha = 0.80). Scores ranged from 0 to 100, with 100 representing maximum worry.

Predictor Variables
Axillary lymph node dissection was the principal variable of interest in predicting outcomes. Because some form of axillary sampling occurs during mastectomy, we assumed that all women who had the entire breast removed also had axillary dissection (except women with simple mastectomy, who were considered as not having axillary dissection unless their pathology report noted lymph nodes). To the extent that women undergoing mastectomy did not have any axillary surgery, this assumption is conservative and would underestimate the effects of axillary dissection on outcomes. No women received sentinel lymph node biopsies. Data on the level of axillary sampling were missing or unreliable. In exploratory analyses, we found that the number of lymph nodes removed, a proxy for level of dissection, was not significantly related to outcomes (data not shown). Determinants of axillary dissection in this cohort have been described elsewhere. We used the Charlson index to develop a comorbidity index based on conditions noted before diagnosis. Because the Charlson Index does not include arthritis, we used data from the medical record to define this condition (yes/no).

Baseline physical and mental function were measured using patient self-reported responses to the MOS SF12 physical and mental health function scales for the period immediately preceding breast carcinoma diagnoses. We also used the mental health scores (sadness and anxiety) preceding diagnosis to control for long-term worries about recurrence. Difficulties with arm functioning (yes/no) were also a predictor of physical functioning, impact of breast carcinoma, and worry about recurrence outcomes.

Controlling Variables
We included factors that could potentially confound relationships between axillary dissection and outcomes. Age was a continuous variable. Race was categorized as black or white. There were less than 1% English-speaking Asian or Hispanic women; these women were considered with whites for analysis. Education was categorized as having a high school or greater education versus a less than high school education. We used marital status at the time of initial breast carcinoma treatment as a proxy for social support. Local treatment included mastectomy, breast conservation and radiation, or breast conservation only. Chemotherapy was prescribed for 9% of the sample, and was not significantly related to any outcome except worry about recurrence, and is only included in the final models for that outcome. Tamoxifen, although used by 62% of women, was also not related to outcomes (data not shown). Recurrence was ascertained by self-report (yes/no). Because the recurrence rate was very low 2 years after surgery, this variable was unstable in regression models and was not included. In addition, we included geographic region to control for the effects of other unobserved factors that may influence practice and outcomes.

Statistical Analysis
Bivariate relationships were examined using one-way analysis of variance and chi-square statistics. To account for repeated measurements and intrapatient correlation of outcomes, we used generalized linear estimation equation models to calculate adjusted effects. All variables that were related to axillary dissection and/or arm problems and outcomes were entered into the models to control for confounding. Age, race, education, stage, initial treatment, and region were retained in the final models. Other variables were only retained if they
were statistically significant in one or more models or if they substantially changed the magnitude of other coefficients. The relative impact of different factors on outcomes was evaluated by comparisons of the standardized regression coefficients. The model of fit was assessed using a pseudo $R^2$.

**RESULTS**

Sixty-six percent of the women in this cohort received breast-conserving surgery (Table 1). The cohort was predominantly white and 73% underwent axillary sampling. Sixty percent reported arm problems at some time in the 2 years after initial treatment—83% of those who underwent axillary surgery and 17% of those who did not have this procedure ($P = 0.0001$). Women who reported arm problems in the 2 years postsurgery also reported using significantly more physical therapy services (22% vs. 6%, $P < 0.0001$) and received slightly more family help (23% vs. 17%, $P = 0.07$) than women without arm problems. Average levels of pretreatment functioning were fairly high in this population and declined only modestly over time. Women’s ratings of the impact of breast carcinoma on their lives were fairly low and declined significantly over time. Conversely, women worried more about recurrence as time elapsed since their initial surgery, although levels of worry were quite low (Table 2). Compared with women who did not have axillary dissection, women who underwent axillary dissection had significantly more arm problems at all points in time and their arm problems increased over time.

**Arm Problems**

The single strongest independent predictor of long-term arm problems was axillary dissection, followed by preexistent arthritis and not being married (Table 1).
3. The cumulative risk of having arm problems at 2 years posttreatment was three times higher (relative risk [RR] 3.01, 95% confidence interval [CI] 1.94–4.67) for women who underwent axillary surgery than for women who did not have axillary procedures, controlling for other factors, and the effects of axillary dissection were linear over time. Women with arthritis were 41% (RR 1.41, 95% CI 1.06–1.87) more likely to report arm problems 2 years after treatment than women without arthritis. The effects of arthritis and axillary dissection were multiplicative (Fig. 2).

**Physical and Mental Health Domains**

The primary long-term determinate of lower physical and mental functioning was postaxillary dissection arm problems (P = 0.0001 and 0.04, respectively), controlling for other factors (Table 3). For instance, women who reported arm problems had adjusted physical function scores of 40, whereas women without arm problems had adjusted scores of 44 (P ≤ 0.0001). Although physical function declined over time for all women, the effect of arm problems on diminishing physical functioning was constant over the 2 years of observation. Of note, the type of initial surgical or adjuvant treatment did not affect physical and mental health outcomes.

**Impact of Breast Carcinoma**

Women who reported arm problems rated the impact of their breast carcinoma on their lives as being more severe than women without posttreatment arm problems (P = 0.0006), controlling for other factors. Although the impact of carcinoma diminished for women as time elapsed since their initial treatment,
the effect of arm problems on impact was seen in all time periods (Table 3).

**Fears of Recurrence**
Undergoing axillary dissection did not lead to less fear about recurrence. Consistent with prognosis, women diagnosed with Stage 2 disease had substantially higher levels of worry about recurrence than women with Stage 1 disease ($P < 0.04$).

**DISCUSSION**
In this cohort of older women with Stage 1 and 2 breast carcinoma, axillary surgery significantly increased the risk of having arm problems in the 2 years after initial treatment. Arm problems, in turn, had consistent negative effects on health-related quality of life over the 2 years posttreatment. These harms were not offset by any benefit in terms of decreasing worry about recurrence. Physical function, as measured by the MOS physical components score, was four points lower for women who had axillary surgery than for those without axillary procedures. This long-term decrement in function corresponds to other scenarios (e.g., living with untreated asthma, suffering from migraine headaches, or a 30% increase in probability of

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**TABLE 3**
**Adjusted Estimates of the Effects of Axillary Dissection and Arm Function and Other Variables on Health-Related Quality of Life Outcomes over the 2 Yrs of Postinitial Treatment for Stage 1,2 Disease**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Arm problems</th>
<th>Physical component score, standardized regression coefficients (SE)</th>
<th>Impact, standardized regression coefficients</th>
<th>Worry about disease recurrence, standardized regression coefficients</th>
<th>Mental component score, standardized regression coefficients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>NS</td>
<td>$-0.0105 (0.02)$</td>
<td>$-0.1900 (0.03)^b$</td>
<td>$-0.0965 (0.04)^c$</td>
<td>$0.0457 (0.03)$</td>
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<td>Race</td>
<td></td>
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</tr>
<tr>
<td>White</td>
<td>1.00</td>
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<td></td>
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<td></td>
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<tr>
<td>Black</td>
<td>1.12 (0.72–1.74)</td>
<td></td>
<td>$-0.0194 (0.03)$</td>
<td>$-0.0210 (0.03)$</td>
<td>$-0.0606 (0.03)^c$</td>
</tr>
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<td>Education</td>
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<td></td>
</tr>
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<td>High school</td>
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<td></td>
<td></td>
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<tr>
<td>More than high school</td>
<td>1.00 (0.77–1.33)</td>
<td></td>
<td>$-0.0391 (0.02)$</td>
<td>$0.0821 (0.03)^c$</td>
<td>$0.0471 (0.04)$</td>
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<tr>
<td>Marital status</td>
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<tr>
<td>Married</td>
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<tr>
<td>Single</td>
<td>1.33 (1.02–1.74)^c</td>
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<td>$-0.0208 (0.02)$</td>
<td>$0.0410 (0.03)$</td>
<td>$0.0389 (0.04)$</td>
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<td>I</td>
<td>1.00</td>
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<tr>
<td>II</td>
<td>1.30 (0.94–1.80)</td>
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<td>$-0.0186 (0.02)$</td>
<td>$0.0652 (0.03)^c$</td>
<td>$0.0797 (0.04)$</td>
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<td>Axillary dissection</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>3.01 (1.94–4.67)^b</td>
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<tr>
<td>Chemotherapy</td>
<td></td>
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<tr>
<td>No</td>
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<tr>
<td>Yes</td>
<td>0.1195 (0.05)^c</td>
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<td>Arthritis</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>1.41 (1.06–1.87)^c</td>
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<tr>
<td>Arm problem</td>
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<tr>
<td>No</td>
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<tr>
<td>Yes</td>
<td>$-0.1040 (0.02)^b$</td>
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<td>Charlson index</td>
<td>0.0819 (0.06)</td>
<td></td>
<td>$-0.1052 (0.03)^b$</td>
<td>$0.0795 (0.02)^b$</td>
<td>$0.0033 (0.04)$</td>
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<td>Prediagnosis physical functioning</td>
<td>$-0.0098 (0.00)^b$</td>
<td></td>
<td></td>
<td>$-0.0208 (0.03)$</td>
<td>$0.01789 (0.03)$</td>
</tr>
<tr>
<td>Prediagnosis sadness</td>
<td></td>
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<tr>
<td>Prediagnosis nervousness</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mos between surgery</td>
<td>0.0698 (0.06)</td>
<td></td>
<td>$-0.1825 (0.02)^b$</td>
<td>$0.0633 (0.04)$</td>
<td>$0.0015 (0.02)$</td>
</tr>
<tr>
<td>and interview</td>
<td>8.7</td>
<td>45.3</td>
<td>12.2</td>
<td>8.9</td>
<td>18.0</td>
</tr>
</tbody>
</table>

$OR$: odds ratio; CI: confidence interval; SE: standard error.

* Estimates based on linear models with correlation matrix of outcomes over time using generalized estimation equations, controlling for insurance, treatment, and region.

$^b P < 0.001$.

$^c P < 0.05$. 

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being hospitalized in the next 6 months).27 Unless other benefits are demonstrated for axillary lymph node dissection in the older population, these data suggest that clinically meaningful risks exist and may mitigate the routine use of this procedure.

This conclusion is supported by the results of previous research.12,13,28–33 In our cohort, 60% of women reported arm problems over the 2 years after initial treatment. Maunsell et al.13 observed comparable levels of arm morbidity. Others have noted that more than one-third of women experience lymphedema after axillary surgery12,34 and that a majority report arm pain.31 These limitations have adversely affected the quality of life.31,35–37 Using a decision analytic approach, Parmigiani et al.28 concluded that axillary dissection after breast conservation has an overall negative impact on the quality-adjusted survival of older women.

Levels of illness and functional capacity before a diagnosis of breast carcinoma strongly predicted all posttreatment outcomes. The prevalence of two or more chronic problems, such as arthritis, hypertension, heart disease, or diabetes, increases with age.5 These illnesses interact with breast carcinoma treatments to affect subsequent function and survival.20,38–41 In the current study, arthritis was an independent and multiplicative predictor of posttreatment arm problems, and arm problems increased the risk of lower functional status outcomes. Ultimately, long-term decrements in physical function affect the activities of daily living that are critical to an older woman’s ability to live independently.40,42 The higher rates of use of rehabilitative services and family support that we observed may also have a broader economic and family impact.

Despite considerable limitations in function, women’s preferences for axillary dissection may also be important in decisions about use of this procedure. Galper et al.43 used hypothetical scenarios and determined that two-thirds of women would accept a 40% risk of arm dysfunction to gain prognostic information, even if it would not have changed treatment. We hypothesized that axillary dissection would provide a survival benefit in terms of reassurance and improved mental health outcomes to women, but we failed to confirm this idea in our prospective cohort.

The adverse impact of axillary dissection and subsequent arm problems, the absence of survival benefit attributable to removal of axillary lymph nodes,44–48 increasing rates of detection of small, lymph node-negative tumors by mammography,49 and the trend for treatment recommendations becoming more independent of histologic lymph node status except in selected subsets of women45,48,50,51 suggest that the role of axillary surgery should be reexamined in older women. Our study predated the general use of sentinel lymph node biopsy.11 It is important to assess long-term arm functioning of older women undergoing this newer procedure. Preliminary data suggest that sentinel biopsies result in less arm dysfunction than full dissections.52–54 Therefore, older women may be an appropriate group in which to consider the use of sentinel lymph node biopsy.55,56

Our results have potential implications for efforts to enhance the enrollment of older women into clinical trials. These trials often require pathologic information from axillary surgery. However, if this procedure has adverse effects on the quality of life, eligibility criteria may need to be relaxed to achieve success in recruiting older women into important treatment trials.28

There are several caveats that should be noted in interpreting our results. First, our study used observational data in selected regions. Although overall consent and follow-up rates were very good, women who survived and were eligible for long-term follow-up were generally younger and healthier than the study sample. However, any sampling bias should underestimate the effects of axillary dissection and arm problems in more general populations of older women. Our observational design has the potential for confounding by unmeasured factors that might affect treatment and outcomes. However, the strength and consistency of effects are unlikely to be totally explained by residual confounding. Because there is
geographic variation in treatment patterns, it will be important to replicate our results in other samples. By assuming that all women having mastectomy had axillary dissection (except simple mastectomy), we may have overestimated the degrees of impairment, as might be detected with physical measurements and detailed questionnaires and weight measurement, would also have underestimated the true effects of axillary procedures on outcomes. In addition, we were not able to differentiate the impact of the level of axillary surgery and our results predate the use of sentinel lymph node biopsy. Our definition of arm problems relied on patient self-report and only captured gross deficits. This lack of sensitivity to lesser degrees of impairment, as might be detected with physical measurements and detailed questionnaires and weight measurement, would also have underestimated the impact of arm difficulties on outcomes.

To limit respondent burden, we used truncated measures to assess several variables, potentially limiting the ability to detect small effects on outcomes. For instance, our failure to detect mediating effects of social support on outcomes may be due to the use of marital status as a proxy measure of social support. The two items used to measure worry about recurrence, which were drawn from a previously validated scale with very good reliability, may have limited our ability to detect differences in this outcome. Other instruments, including breast carcinoma-specific tools, may have noted other outcomes. We focused on general measures of quality of life to detect physical function and arm-related problems and to enhance comparisons with other populations.

We used a longitudinal design to describe factors that were causally related to quality of life outcomes and observed a strong temporal relationship between axillary surgery and arm problems. Although these data suggest a causal pathway, they should be confirmed in other prospective studies and balanced against other clinical factors. For instance, Lash et al. demonstrated that older women who received prognostic evaluation (i.e., axillary lymph node dissection and estrogen receptor testing) had a 30% lower risk of 10-year breast carcinoma-specific mortality, independent of other factors. We cannot rule out the hypothesis that women with poorer quality of life rated their arm problems as being more severe than women with a better quality of life.

Overall, arm problems after axillary dissection had a consistent negative impact on quality of life. Unless axillary staging information will significantly alter treatment recommendations or provide women with more precise prognostic knowledge that would improve their well-being or other quality of life domains, the risks of axillary dissection, particular among women with preexisting arthritis, may outweigh the benefits in this population. Sentinel lymph node biopsy may be particularly useful in this setting. Until we have more data demonstrating the effectiveness and predictive value of sentinel lymphadenectomy, we support the recommendation that older women be provided detailed information about the potential morbidity of axillary surgery when making initial treatment decisions.

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