Degree of Variability in Performance on Breast Cancer Quality Indicators: Findings From the Florida Initiative for Quality Cancer Care

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Abstract

Purpose: The Florida Initiative for Quality Cancer Care (FIQCC) comprises 11 Florida practice sites that participate in comprehensive reviews of quality of care specific to patients with cancer. Here, we examined site adherence to performance indicators to assess quality of care for patients with breast cancer (BC).

Methods: Quality indicators were scripted on the basis of accepted guidelines from the Quality Oncology Practice Initiative, National Comprehensive Cancer Network, American College of Surgeons, and site-specific expert panel consensus. Comprehensive chart reviews, including both medical and surgical oncology quality measures, were conducted for patients with BC first seen in 2006 by a medical oncologist at one of the sites. Statistical comparisons were made by the Pearson χ^2 exact test, using Monte Carlo estimation.

Results: Charts of 622 patients were reviewed. Of the 34 indicators, seven for medical oncology and four for surgical oncology fell below the 85% level of adherence. A statistically significant difference ($P < .001$) in variation of performance across the sites was found for the following medical and surgical oncology indicators: documentation of menopausal status, family history, informed consent, planned chemotherapy regimen and flow sheet, American Joint Committee on Cancer staging, HER2/*neu* status, reporting of margin orientation and inking of the margins, histological grade, having a sentinel lymph node biopsy for invasive BC, and obtaining a mammogram within 14 months of definitive surgery.

Conclusion: The FIQCC has identified how multiple aspects of BC care can be improved. Findings are being used at the participating institutions to guide quality improvement efforts.

Introduction

In 1999, the Institute of Medicine's National Cancer Policy Board published "Ensuring Quality Cancer Care," a landmark report on quality of cancer care.¹ The Board recommended developing systems to measure and monitor quality of care by means of a core set of indicators. As a result, many initiatives for quality cancer care were started. One such initiative, the National Initiative for Cancer Care Quality (NICCCQ),² was sponsored by ASCO in 2000. The NICCCQ used expert opinion and literature to formulate and assess breast cancer (BC) quality measures for patients presenting with stage I-III disease in five major US metropolitan areas. The 36 quality measures assessed eight components of clinical care, including pathology and documentation. Performance ranged from as low as 13% for referrals to as high as 97% for testing/treatment.³

Building on the NICCCQ goals of assessing and reporting, ASCO sponsored the Quality Oncology Practice Initiative (QOPI)⁴ to provide feedback to medical oncology groups across the United States. QOPI is a practice-based quality self-assessment tool that relies on chart reviews focusing on pathology and chemotherapy documentation, pain assessment, symptom management, and BC-specific indicators. QOPI is now voluntarily used by

> 500 practices nationwide. A study of 71 practices participating in QOPI demonstrated that, by providing feedback about deficiencies, use of QOPI resulted in significant positive changes in aspects of care for which performance was most deficient.⁵

The Florida Initiative for Quality Cancer Care (FIQCC), a physician- and practice-based quality improvement project, was conceived to study the barriers to delivering high-quality cancer care in Florida, the state with the second highest mortality rate from cancer in the United States.⁶ The FIQCC is a consortium of 11 Florida institutions (Appendix Figure A1, online only),⁷ with three academic and eight community sites, that are actively participating in a comprehensive practice-based system of quality self-assessment across a number of cancer types. FIQCC selected quality indicators on the basis of accepted QOPI, National Comprehensive Cancer Network, American College of Surgeons, and site-specific principal investigator (PI) panel consensus indicators. In this study, we assessed adherence to performance indicators among these sites. We hypothesized that variation existed among the sites on specific indicators and that practice volume and age of the patient cohorts, factors that can affect both delivery of care and treatment, also contributed to variation in adherence.

Methods

Representatives from the 11 oncology sites selected quality measures consistent with evidence-, consensus-, and safety-based guidelines that could be abstracted from medical records. The resulting indicators were organized by diagnosis (BC, colorectal cancer, non-small-cell lung cancer) and by domains of care (eg, symptom management). In this article, we focus only on BC results.

Selection of Indicators

A panel of breast medical and surgical oncology experts from the H. Lee Moffitt Cancer Center and Research Institute (Tampa, FL) met monthly for 6 months to formulate breast indicators based on ASCO, National Comprehensive Cancer Network, NCCN, QOPI, and American College of Surgeons guidelines. Panel consensus of the selected quality indicators from PIs, coinvestigators, and collaborative site PIs was required before data collection.

Selection of Practices

The 11 FIQCC study sites, all affiliated with Moffitt (Appendix Figure A1), agreed to provide a qualified medical record abstractor and to follow FIQCC quality standards, data collection forms, and a data collection process. Comprehensive chart reviews were conducted for patients newly diagnosed with a primary invasive BC who had been first seen in 2006 by a medical oncologist at one of the 11 FIQCC sites.

Chart Reviews

When the consortium was formed, the first disease to be examined was colorectal cancer. The number of BC cases was predetermined to match the number of colorectal cancer cases, as there were fewer colorectal cases than BC cases. Charts of patients with BC were randomly selected from among those identified at each site until the predetermined number of charts had been abstracted. This amounted to a total of 19% (622 of 3,275) of the available charts.

Abstraction and Quality Control

Before chart abstraction at each site, an abstractor trainer traveled to each institution and, using sample charts, instructed the on-site abstractor on the specific information to be acquired. Quality control of the data retrieved was maintained through two audits, which were performed by the trainer when abstraction of the assigned total number of charts for review was one third and two thirds complete at each site. We included both medical oncology and surgical oncology quality measures. This study was approved by the institutional review boards at each participating site.

Statistical Analyses

We used descriptive statistics and graphic illustrations to summarize all indicator variables. The compliance proportion, with its 95% CI, was calculated on the basis of exact binomial distribution. Statistical comparisons across sites were made by the

Pearson χ^2 exact test, using Monte Carlo estimation. Logistic regression models were used to evaluate effects of practice site and site volume (low v high, divided by a cutoff point of 300 patient charts to allow for a balanced distribution between the two groups) and age (< 50, 50-70, > 70 years) on each of indicator variables. Volume distribution was based on the estimated total volume of patients with BC per site for 2006. Odds ratio, with its 95% CI, was estimated from the models. All analyses used two-tailed tests of significance, with the significance level set at $P < .001$. On the basis of the NCCN guidelines,³ we predetermined a threshold of 85% to be the goal for the level of concordance with the individual indicators.

Results

The charts of 622 patients (99% female) with invasive BC were reviewed (Table 1). The median age was 60 years (range: 22 to 95). Appendix Table A1 (online only) lists the parameters, quality indicators, and source for each medical and surgical oncology indicator reviewed.

Medical Oncology Indicators

Results pertaining to medical oncology indicators are summarized in Appendix Table A2 (online only). Our results are shown as an overall score for all sites combined, followed by the range for the 11 participating sites.

Table 1. Demographic Data

Characteristic	No.	%
Age, years		
Median		60
Range		22-95
Race/ethnicity		
White/Caucasian	501	80.5
Black/African American	57	9.2
Asian/Pacific Islander	4	0.6
Missing race	60	9.7
Hispanic/Spanish/Latino	37	6
Not Hispanic/Spanish/Latino	176	28
Missing ethnicity	409	66
Sex		
Male	4	0.6
Female	618	99.4
Payer		
Medicare	234	38
Medicaid	33	5
Private	306	49
Self-pay	15	2
Indigent/charity	27	4
Missing	7	2
Stage		
I	246	43
II-III	297	51
IV	35	6

All 622 charts were assessed for family history and menopausal status, with family history documented in 80% (495 of 622; range: 55% to 95%) and menopausal status documented in 49% (307 of 622; range: 15% to 78%) of charts. Of the 88 reported premenopausal women, 11% (10 of 88; range: 0% to 20%) indicated that fertility preservation had been discussed.

We found that 93% (578 of 622; range: 78% to 100%) of charts showed appropriate American Joint Committee on Cancer staging, and these were used for further abstractions. Documentation of the hormone receptor status (estrogen receptor/progesterone receptor) was evident in 100% (578 of 578; range: 98% to 100%) of charts, and 98% (566 of 578; range: 84% to 100%) showed documentation of HER2/*neu* status. Sites had excellent compliance for consideration or discussion of adjuvant hormone therapy for patients with both nonmetastatic and metastatic disease (Appendix Table A2).

Of the 330 patients who received chemotherapy, a discussion of chemotherapy was documented in 96% of patients at stage 1c-III: for stage I (T1c), 18 of 18 patients; for stage II-III, 285 of 297 patients (range: 81% to 100%). Consent was documented in 75% (247 of 330; range: 43% to 100%) and a chemotherapy flow sheet in 96% (316 of 330; range: 81% to 100%) of charts. Among all patients who received neoadjuvant or adjuvant chemotherapy, a planned chemotherapy regimen was documented in 75% (226 of 302; range: 43% to 98%). For charts of patients with nonmetastatic disease and chemotherapy documented, the planned dose of chemotherapy fell within the published regimen range in 75% (155 of 208; range: 40% to 89%). Initiation of adjuvant chemotherapy occurred within 8 weeks of definitive surgery for 84% of patients (233 of 279; range: 33% to 95%). Documentation of a surgical procedure after chemotherapy was shown for 89% (34 of 38; range: 33% to 100%) of patients receiving neoadjuvant therapy. A statistically significant difference in variation of performance across the sites was found for seven of 22 medical oncology quality indicators (Appendix Table A2).

Surgical Oncology Indicators

Surgical oncology results are summarized in Appendix Table A2. With respect to pathologic reporting, there was high (> 90%) compliance for presence of a pathology report and documentation of the American Joint Committee on Cancer or TNM staging, tumor size and grade, status of margins, and hormone receptor status. Pathology quality measure questions were applied only to patients who were staged nonmetastatic, had surgery, and had a pathology report in their medical records; that is, 537 charts of the initial 622 were eligible for analysis of pathology quality indicators. Of those 537 charts, 370 (69%; range: 44% to 90%) had documentation that the specimen was oriented and 474 (88%; range: 54% to 98%) stated that the margins were inked. The American Society of Breast Disease policy statement (June 2005) states that "specimen orientation should be performed on all partial breast excisions for a suspicious or malignant lesion."⁸ Various methods of orientation can be used (clips or suture) providing two points of

orientation (ie, superior, lateral) followed by inking. For purposes of this study, any inking was deemed compliant.

For inclusion in the remaining surgery quality measures, the patient had to have a nonmetastatic invasive cancer and documentation of surgical procedure. Sentinel lymph node biopsy is recommended by the American Society of Breast Surgeons in patients with clinically node-negative (T1N0, T2N0) disease based on palpation of the axilla, with or without axillary imaging.⁹ Extreme age, comorbid conditions, multicentric disease, and invasive tumors < 5 mm or > 5 cm were not considered as contraindications during chart abstraction. Sentinel lymph node biopsy was performed in 82% (447 of 542; range: 62% to 94%) of patients with invasive BC regardless of whether breast conservation or mastectomy was performed. Of the patients with a metastatic sentinel lymph node biopsy, 79% (123 of 156; range: 62% to 96%) went on to have a complete axillary node dissection. Isolated tumor cells in the sentinel lymph nodes were not considered node positive. Data reflecting micrometastatic, macrometastatic, or nodal burden were not available but may have confounded the compliance with performing a complete axillary lymph node dissection.

Sites showed moderate compliance regarding patients obtaining mammograms within 14 months of definitive surgery (77%; range: 26% to 98%). Although the four male patients in the series had mastectomies, they were excluded from this analysis. The rate of referral to radiation treatment within 1 year of definitive surgery was high (97%; range: 80% to 100%).

Statistically significant variations across practices were found for margin orientation, inking of the margins (Appendix Figure A2, online only), histological grading, performance of sentinel lymph node biopsy, and obtaining a mammogram within 14 months of definitive surgery.

Indicators by Volume and Age

Because patient volumes can affect delivery of health care, assessments of all indicators were made by dividing the sites into those with low volume (eight sites) and those with high volume (three sites). A marginally significant difference ($P < .05$) between all high- and low-volume sites was evident for two indicators. The high-volume sites outperformed the low-volume sites for documentation of inked margins. In contrast, the low-volume sites outperformed the high-volume sites on use of sentinel lymph node biopsy.

When stratified by age (< 50, 50-70, and > 70 years), statistically significant differences were evident for three of 34 indicators: documentation of family history, documentation of menopausal status, and obtaining a mammogram within 14 months of surgery. For family history, patients younger than 50 years had better adherence than those in 50 to 70 years age group (odds ratio [OR] = 1.87; 95% CI: 1.1 to 3.2) and the > 70 years group had poorer adherence than the < 50 group (OR = 0.49; 95% CI: 0.3 to 0.9). Likewise, for documentation of menopausal status, the < 50 group had better adherence than the 50 to 70 group (OR = 1.83; 95% CI: 1.2 to 2.7) and the > 70 group had worse adherence than the < 50 group (OR = 0.38; 95% CI: 0.2 to 0.6). There was no significant

difference between the older groups for either of these two indicators compared with the 50 to 70 year group. Interestingly, patients > 70 years of age had a higher adherence to obtaining mammograms within 14 months of surgery than patients age 50 to 70 years (OR = 2.07; 95% CI: 1.1 to 3.0) or < 50 years (OR = 2.01; 95% CI: 1.0 to 3.9).

Discussion

This article represents a comprehensive examination, based on process indicators, of the quality of BC care provided at the 11 FIQCC practice sites. In addition to identifying numerous areas of excellence, our systematic review of medical oncology charts identified areas that needed improvement. We will discuss those indicators with less than optimal performance, as they represent important targets for quality improvement efforts. Variability among the sites was found for certain indicators, but in general, these differences did not correspond to the volume of patients seen at a site. Likewise, patient age (which is strongly related to menopause status) was also generally unrelated to performance.

In 2002, ASCO's QOPI included guidelines on chemotherapy consent and documentation. In our review, overall compliance of 75% of charts was reached for both documentation of consent and planned chemotherapy regimen. Exploring our data further, there was significant ($P < .001$) intersite variance for both parameters. Informed consent is a significant aspect of the medical oncologist's role,^{1,10} and clinicians must be able to adequately inform patients regarding specifics of the recommended chemotherapy regimens.

Equally as important is an explanation of why a patient may not be appropriate for chemotherapy. We recognize that factors such as multiple comorbidities, poor Eastern Cooperative Oncology Group performance status, and postoperative complications play key roles in the chemotherapy decision-making process. Our analysis showed that this indicator (indicator 16 in Table 2) was documented in only 20% of charts, with high intersite variance. Unfortunately, the low sample size makes it difficult to draw firm conclusions.

Low rates of adequate chemotherapy dosing were noted across all sites reviewed, which is concerning, as others^{11,12} have documented that suboptimal therapeutic chemotherapy dosing can lead to worse outcomes. Strong consideration should be given to the administration of adequate doses of chemotherapy to patients with BC as long as it is deemed safe. If inadequate dosing is necessary because of poor performance status or comorbid conditions, then clear documentation of the reasoning should be provided in the medical chart.

Fertility preservation was a prominent measurement, as compliance was low, whereas concordance between the sites was high. Although it was not a specific quality care measure according to QOPI, NCCQ, and FIQCC guidelines, ASCO¹³ and St Gallens¹⁴ have incorporated new guidelines regarding the importance of discussion of fertility preservation during the medical oncology consultation. The FIQCC panel included it as an exploratory indicator and found that documentation of discussions on fertility preservation was low across all sites. We

acknowledge the difficulty in drawing specific conclusions on a small sample size but still recognize this as an area of deficiency.

Perhaps one theme that links these above indicators together is the concept that physicians might consider that the indicators are "implicit" in the medical chart and thus do not require specific documentation. For example, a 65-year-old woman diagnosed with BC is presumed to be postmenopausal, or an individual with multiple comorbidities would always undergo dose reduction for their first cycle of chemotherapy. Continuous measurements of quality indicators with associated feedback regarding the importance of documentation will lead to improvement in quality of cancer care. Therefore, unknown deficiencies such as those identified in this study can be identified, highlighted, and resolved.

With regard to surgical oncology indicators, we identified the need for improvement in margin orientation and inking, use of sentinel lymph node biopsy, and obtaining mammograms in postsurgical follow-up. One explanation for the lack of margin orientation is the continued use of primary surgical excision, as opposed to core needle biopsy, for diagnostic purposes of abnormal imaging. Most surgeons appeared not to have oriented the diagnostic biopsy specimen despite the policy statement from the American Society of Breast Diseases recommending that orientation (including inking) be performed on all surgical excision specimens if suspicious.⁸ If the diagnosis returns as malignant, then the specimen would be listed in our data abstraction as "no margin orientation." Similarly, BC surgery can be performed in an ambulatory surgery center where on-site pathology is not available; thus the specimens would be placed in formalin without inking unless the surgeon performs the inking.

Use of sentinel node biopsy is dependent on several factors. Yet many experienced general surgeons still have not obtained the additional training required to perform this procedure. However, in our data, the high-volume centers showed significantly less frequent use of this procedure. One could rationalize that a selection gradient, or bias, might explain these results, such as the case of a frail elderly patient in whom the knowledge of the true sentinel node status would not change disease management or increase the use of preoperative axillary ultrasound with fine needle aspiration.

Failure to obtain a mammogram within 14 months of definitive surgery might be the result of missing documentation rather than not actually having the test performed. Traditionally, mammograms are under the purview of the surgeon, who might not forward the results to their medical oncology partners; thus information would not be included in a patient's medical chart (for abstraction).

The use of medical oncology charts as the sole source of data acquisition serves as a limitation of this study with regard to surgical/pathologic or radiation oncology indicators. This raises questions regarding whether problems with documentation can alter the results and limit data interpretation. As previously reported, supplementation of patient recorded data to physician records can result in quality scores increasing by 5% to 10%.^{15,16} This effect is somewhat minimized within the

FIQCC by the inclusion of patient history and new patient questionnaires. Another limitation is the small sample sizes for some of the indicators, which easily could skew the interpretation of compliance. In addition, depending on the level of evidence-based support and physician/center prioritization, some indicators will be more heavily weighted in the clinic than others, thus affecting the outcomes of some measurements. Although limitations do exist, the main strengths of the FIQCC are the diversity across sites, (ie, academic *v* private practice) and their broad geographic distribution, which make the results more broadly applicable.

All institutions were provided with the results shown in the figures and were un-blinded as to which letter (A-K) corresponded to their particular site. These findings are now being used at the participating institutions to guide quality improvement efforts. We anticipate that a comparison of the pre- and postimplementation data on those indicators targeted for improvement will show significant enhancements in quality of care over time. With methods developed and implemented as part of this future project and with refinement of the indicators, we plan to develop a model that could be used effectively by other local and regional networks throughout the United States to improve the quality of care for women with BC.

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