Challenges in the Delivery of Quality Breast Cancer Care: Initiation of Adjuvant Hormone Therapy at an Urban Safety Net Hospital

By Meaghan M. Crowley, MD, Molly E. McCoy, MPH, Sharon M. Bak, MPH, Sarah E. Caron, MPH, Naomi Y. Ko, MD, Lisa A. Kachnic, MD, Faber Alvis, and Tracy A. Battaglia, MD, MPH

Boston Medical Center; and Boston University School of Medicine, Boston, MA

Abstract

Purpose: Breast cancer treatment disparities in racial/ethnic minority and low-income populations are well documented; however, underlying reasons remain poorly understood. This study sought to identify barriers to the delivery of quality breast cancer treatment, addressing compliance with the National Quality Forum (NQF) quality metric for adjuvant hormone therapy (HT; administration of HT within 365 days of diagnosis in eligible patients) at an urban safety net hospital.

Methods: This retrospective, observational study included women diagnosed with nonmetastatic, T1c or greater, estrogen and/or progesterone receptor–positive breast cancer from 2006 to 2008. Data sources included the hospital cancer registry and electronic medical record. Compliance with the NQF quality metric was defined as HT prescription within 365 days of diagnosis. Bivariate analysis compared compliant with noncompliant patients. Qualitative analysis assessed reasons for delayed compli-

ance (HT at > 365 days) and never compliance (no HT at 4 years).

Results: Of 113 eligible patients, the majority were racial/ethnic minority (56%), stage II (54%), unmarried (60%), and had public or no insurance (72%). Sixty-four percent were compliant, and 36% were noncompliant. Of the noncompliant, 78% had delayed compliance, and 22% were never compliant. Noncompliant patients were significantly more likely to be Black, Hispanic, foreign-born, and stage III at diagnosis. Ten reasons for delayed compliance were identified, including patient- and system-level barriers. Most patients (56%) had more than one reason contributing to delay.

Conclusion: Urgently needed interventions to reduce disparities in breast cancer treatment should take into account obstacles inherent among immigrant and indigent populations and complexities of multidisciplinary cancer care.

Introduction

Disparities in breast cancer mortality persist, with higher mortality rates in nonwhite women even when compared with white women at the same stage at diagnosis.¹⁻³ Similar findings have been demonstrated for low-income and less educated populations, regardless of race/ethnicity.⁴⁻⁶ The underuse of standard therapy among vulnerable populations may be one reason for this ongoing disparity.⁷ For example, the Early Breast Cancer Trialists' Collaborative Group reported a 31% decrease in annual breast cancer death rates with 5 years of the introduction of adjuvant tamoxifen.⁸ However, the rate of receipt of adjuvant hormonal therapy (HT) in racial/ethnic minority women with breast cancer has been shown to be significantly lower than in white women, and members of minorities are more likely to miss doses when prescribed HT.⁹⁻¹²

In an effort to monitor and improve the delivery of breast cancer care, the National Quality Forum (NQF) endorsed quality metrics for breast cancer treatment in 2007 developed by the American College of Surgeon's Commission on Cancer (CoC), ASCO, and the National Comprehensive Cancer Network (NCCN).^{13,14} These include a metric for HT that states, HT should be administered within 365 days of diagnosis in women with American Joint Committee on Cancer (AJCC) classification by tumor size (T), lymph node (N), and metastasis (M) of T1cN0M0, or stage II or III, estrogen receptor (ER)

and/or progesterone receptor (PR) –positive breast cancer. These metrics, now used to evaluate the care provided at CoC-accredited cancer programs, are published online in the Cancer Program Practice Profile Reports (CP³R). Poor compliance with these quality metrics has been demonstrated in minority and low-income populations, yet the underlying reasons remain poorly understood.¹⁵

Underserved populations face unique challenges, and oncologists currently have a poor understanding of individual barriers to recommended care, limiting the ability to improve quality of care and outcomes. In this era of accountable care, understanding why standards of care are not met is important at the patient level, especially at institutions that care for vulnerable populations. At our urban safety net, CoC-accredited hospital, we noted a low performance rate on the NQF quality metric for HT administration between 2006 and 2008. Therefore, we sought to investigate patient and system barriers relating to low compliance with this standard to inform quality improvement efforts that would allow us to meet CoC standards.¹³

Methods

We conducted a retrospective observational study of eligible patients with breast cancer from 2006 to 2008 at Boston University Medical Center (BUMC), the largest safety net medical

center in New England, serving a racially and ethnically diverse, low-income population. We used data from our hospital's electronic medical record (EMR), consistent with methods used to create the CP³R. The BUMC institutional review board approved this quality improvement study.

Study Population

Inclusion criteria for female patients with breast cancer were based on eligibility for HT as defined by the NQF metric.¹⁴ Eligible women were diagnosed with AJCC T1cN0M0 or stage II or III, ER- and/or PR-positive breast cancer between 2006 and 2008.

Data Collection

Eligible patients were identified by the CP³R provided to our institution by the CoC. Two internal data sources were used for this study: (1) The hospital cancer registry was used to obtain sociodemographic and clinical data on all patients. This included age; race/ethnicity; health insurance at time of diagnosis; primary language; birth country; marital status; date of diagnosis; AJCC stage at diagnosis; clinical site of diagnosis; dates and type of first surgery; and dates of receipt of radiotherapy (RT), chemotherapy, and HT. (2) Chart abstraction was performed from the hospital's EMR for patients who were noncompliant with the HT quality metric. Chart abstraction, using a standard form, captured sociodemographic and clinical data not available from the registry, including country of primary residence; site of primary care; comorbid medical conditions; dates and types of diagnostic procedures; dates and types of surgeries; RT, chemotherapy, and HT recommendations and dates of receipt; dates of appointment no-shows or cancellations; and patient/provider comments recorded in provider notes.

The primary study outcome was compliance with the NQF quality metric for HT. Compliance status was determined by the number of days from breast cancer diagnosis (defined as date of diagnostic biopsy) to HT initiation (defined as date of HT prescription or documented receipt of HT), where ≤ 365 days was compliant and more than 365 days was noncompliant. Noncompliant patients were further classified as delayed compliant (HT initiation at > 365 days) or never compliant (no documentation of HT at 4 years). Patients were monitored through chart abstraction for 4 years or until a definitive event, including patient receiving HT, patient declining HT, provider determining that HT was contraindicated, or patient leaving the health system.

Chart abstraction forms were used to capture reason for noncompliance with the HT quality metric, in an attempt to identify modifiable reasons for delays in care. Pilot codes were developed from the first 10 charts abstracted, on the basis of suggestions from literature review and comments recorded from chart abstraction, to categorize reasons for delayed compliance and never compliance. Additional codes were identified through an inductive process with each set of 10 charts. Reasons for delayed compliance were not mutually exclusive, whereas reasons for never compliance were mutually exclusive. These categories were reviewed for homogeneity, and classification of

individual patient's reason was confirmed through consensus with all authors.

Data Analysis

The compliance status of all eligible patients identified by the hospital's CP³R was verified by cross-reference with the hospital cancer registry dates. Patients deemed noncompliant on the basis of the cancer registry and/or the CP³R underwent chart abstraction. Patients with ≤ 365 days from diagnosis to HT based on chart abstraction were reclassified as compliant ($n = 3$).

Sociodemographic differences between compliant and noncompliant groups were identified using the χ^2 or Fisher's exact test. Measures of central tendency, t tests, and one-way analysis of variance were used to describe and examine differences in HT delay between stratified groups. Statistical tests were two-tailed, with a significance level set at $P < .05$. All data were analyzed using SAS version 9.1.3 (SAS Institute; Cary, NC). Descriptive statistics were used to describe reasons for noncompliance.

Results

The CP³R identified 113 patients eligible to receive HT between 2006 and 2008. After cancer registry data review, five patients were reclassified from compliant to noncompliant, as no HT date was recorded in the registry to confirm compliance. After EMR chart abstraction, three additional patients were reclassified from noncompliant to compliant. These three patients had received HT within 365 days of diagnosis; two had an incorrect HT date recorded in the cancer registry, and one had an incorrect diagnosis date according to EMR documentation. Overall, 72 patients (64%) were compliant, and 41 (36%) were not compliant. Among the noncompliant group, 32 (78%) eventually received HT (delayed compliant), and only 9 (22%) never received HT (never compliant).

Table 1 describes the baseline characteristics of patients by compliance status. Among all patients, the mean age was 57 years (standard deviation [SD] = 12 years). The majority were between 50 and 64 years old, racial or ethnic minority (35% Black, 15% Hispanic, 5% Asian), English speaking (72%), unmarried (60%), born in the United States (52%), had public or no health insurance (76%), and were stage II at diagnosis (54%). Compared with compliant patients, noncompliant patients were less likely to be white (24% *v* 56%, $P = .002$), but more likely to be born outside of the United States (61% *v* 40%, $P = .03$), stage III at diagnosis (27% *v* 13%, $P = .05$), and diagnosed in 2007 or 2008 ($P = .002$). No significant difference was observed in age, language, marital status, insurance, or clinical site of diagnosis.

The mean number of days from diagnosis to initiation of HT (data not shown) was 470 (SD = 75) for patients with delayed compliance, compared with 213 (SD = 91) for compliant patients ($P < .001$). When all patients were stratified by AJCC stage at diagnosis, the mean number of days from diagnosis to receipt of HT was 201 (SD = 114) for those diagnosed at stage I, 266 (SD = 130) at stage II, and 403 (SD = 156) at stage III; the differences between these groups were significant

Table 1. Patient Characteristics by Compliance Status

Characteristic	Total (N = 113)		Compliant (n = 72)		Noncompliant (n = 41)		P
	No.	%	No.	%	No.	%	
Age (years)							.61
< 50	35	31	24	33	11	28	
50-64	51	45	30	42	21	51	
≥ 65	27	24	18	25	9	22	
Race/ethnicity							.002*
Asian	6	5	5	7	1	2	
Black	40	35	21	29	19	46	
Hispanic	17	15	6	8	11	27	
White	50	44	40	56	10	24	
Language							.07
English	81	72	55	76	26	63	
Spanish	14	12	5	7	9	22	
Other	18	16	12	17	6	15	
Married	45	40	14	34	31	43	.32
Non-US born	54	48	29	40	25	61	.03*
Insurance status							1.0
Private	27	24	17	24	10	24	
Public	81	72	52	72	29	71	
Uninsured	5	4	3	4	2	5	
Stage at diagnosis							.05*
I	32	28	25	35	7	17	
II	61	54	38	53	23	56	
III	20	18	9	13	11	27	
Diagnosed at Boston Medical Center	99	88	64	88	35	85	.58
Year of diagnosis							.002*
2006	37	33	32	44	5	12	
2007	39	35	21	29	18	44	
2008	37	33	19	26	18	44	

* Significant result.

($P < .001$). There was no difference in time to HT when comparing patients who received adjuvant chemotherapy with those who received neoadjuvant chemotherapy.

Ten reasons for delayed compliance were identified; these were not mutually exclusive. Table 2 displays the reasons for delayed compliance, number of patients, and definition or case examples for each reason. Figure 1 displays the distribution of patients across the 10 reasons identified for HT delay, ranked in order of the longest to shortest delay. More than one reason for delay was identified for 18 patients (56%). Patient request or social factors ($n = 8$) included documented patient request to receive a therapy at a date later than suggested by the provider or social factors interfering with the ability to receive treatment. For example, this included one patient requesting surgery delay for travel outside of the country to attend a wedding. Another patient delayed return to clinic after diagnostic biopsy despite documented attempts to contact her; on returning, it was documented that the patient's daughter had hesitated to bring the patient to receive the diagnosis due to memories of a family member who had died of breast cancer. Significant delay as a

result of multiple breast surgeries ($n = 5$) was defined as delay caused by two or more primary breast surgeries over more than 3 months. These were patients with positive margins after initial surgery at our institution or an outside hospital. Trastuzumab completion ($n = 8$) accounted for delay in patients with human epidermal growth factor receptor 2 (HER2) –positive breast cancer treated with trastuzumab in whom HT was not started until completion of 1 year of trastuzumab. This occurred in eight of 13 HER2-positive patients. Patients with delay due to multiple no-shows ($n = 6$) missed more than five scheduled appointments, in some cases a first consultation or the oncology appointment before the one at which HT was started. An outside hospital diagnosis ($n = 5$) resulted in time delay between diagnosis and initial visit at our hospital. Patients with delay due to testing to determine treatment eligibility ($n = 6$) experienced treatment decision delay while awaiting guidance from additional test results. Patients with financial delay ($n = 2$) experienced postponement of treatment as a result of financial or insurance issues. Evaluating disease status or stage ($n = 3$) included patients with treatment delayed for work-up

Table 2. Reasons for Delayed Compliance (n = 32)

Reason	Patient n	Description or Selected Case Examples
Patient request or social factors	8	Elective travel outside of the country, anxiety over receiving the diagnosis
Multiple breast surgeries	5	Two or more primary breast surgeries over more than 3 months
Trastuzumab completion	8	Specific provider documentation that trastuzumab completion was necessary prior to HT initiation
Multiple no-shows	6	More than five scheduled appointments missed
Outside hospital diagnosis	5	Delay between diagnosis at outside hospital and evaluation at our hospital ranging from 2 weeks to 3 months
Testing to determine treatment eligibility	6	Results awaited prior to chemotherapy regimen determination, including Oncotype DX, CYP2D6 Workup to rule out deep vein thrombosis or endometrial cancer
Financial	2	First surgery rescheduled due to financial issues HT initiation postponed because of lack of insurance
Evaluating disease status or stage	3	Work-up to rule out metastatic disease
Treatment adverse effects	8	Neutropenic fever requiring hospital admission, poor skin healing after radiation therapy, cellulitis at surgical site
Active comorbidities	4	Documentation of treatment delay as a result of uncontrolled hypertension, pregnancy, atypical chest pain

Abbreviation: HT, hormone therapy.

of possible metastatic disease. Treatment adverse effects (n = 8) included complications of cancer therapy that prolonged the treatment course. Active comorbidities (n = 4) included medical conditions not directly related to breast cancer or its treatment that were acutely active during this period, resulting in delayed cancer treatment.

As seen in Figure 1, the most common reasons for delay were patient request or social factors, trastuzumab completion, and treatment adverse effects, each of which contributed to delay in eight patients (25%). Reasons associated with the longest delay included patient request or social factors (mean of 516 days from diagnosis to HT receipt) and multiple surgeries (503 days). Reasons associated with the shortest delay included treatment adverse effects (420 days) and active comorbidities (411 days).

Three mutually exclusive reasons were identified for never compliance: HT contraindicated as determined by provider (n = 3), patient declined HT (n = 3), and patient moved outside of the system (n = 3). Examples of HT contraindication included terminal illness or immobility resulting in a poor risk-benefit ratio. Patients who declined HT had clear statements documented in the medical record to indicate that they

refused recommended adjuvant therapies. Three patients moved out of our system to return to their home county, each with provider documentation recommending that they pursue HT with their new providers.

Discussion

This quality assurance breast cancer treatment study was performed at an urban safety net institution, representing a diverse, vulnerable population at risk for poor outcomes. We confirmed through chart abstraction that only 64% of women eligible to receive HT for the treatment of localized breast cancer were compliant with the NQF metric. The noncompliant women represented the population most at risk for poor outcomes, as they were more likely to be of a minority race/ethnicity, born outside of the United States, and stage III at diagnosis. Most women eventually received HT, however, not within the time frame recommended for quality care. Reasons for delayed therapy were complex and reflective of challenges inherent in caring for a low-income population, yet are amenable to health system improvement initiatives.

Our compliance rate of 64% is comparable to those from studies of similar populations, including Medicaid patients in

Figure 1. Reasons for delay in hormone therapy by type, number, and length of delay among delayed compliant group (n = 32).

North Carolina and New York for whom compliance rates were 70% and 68%, respectively.^{16,17} In contrast, higher compliance rates of 79% to 82% were observed in a majority-white population in a multi-institutional clinical trial.¹⁸ Our study is the first to explore individual patient-level reasons to better understand this difference. It is noteworthy that most women in our study were found to have received HT, albeit many outside the recommended time frame. Whereas reasons for never compliance were largely nonmodifiable (such as patients moving out of the country) and consistent with other studies,^{19,20} the reasons for delays in care, though multifactorial, are potentially modifiable through innovations in care delivery.

Despite a largely immigrant population, we found no difference in insurance status between compliant and noncompliant patients. This is in contrast to prior literature, which suggests that lack of insurance may contribute to lower access to care in immigrant populations.^{21,22} In fact, our study was conducted during a transition period of health insurance reform in Massachusetts that went into effect in 2006.²³ The low rates of noninsurance throughout the study period (4%) is reflective of successful implementation of near-universal coverage for a safety net population. Yet the high rates of noncompliance in this population suggest that although insurance may be necessary to ensure access to care, it is not sufficient to ensure compliance with quality HT treatment.

Six of the 10 reasons identified for treatment delays relate to complexities of cancer treatment regimens: multiple breast surgeries, trastuzumab completion, testing to determine treatment eligibility, evaluating disease status or stage, treatment adverse effects, and multiple comorbidities. As new discoveries in breast cancer treatment evolve, treatment options continue to expand. An unintended consequence of these options are demonstrated here: delays in the treatment trajectory. For example, at the time of the study, trastuzumab was a novel therapy, and decisions around optimal implementation of treatment were still unknown. This highlights the constant evolution of breast cancer treatment, requiring an urgent need for health systems to monitor practice performance.

Equally important in treatment delays for this vulnerable population were factors reflective of the individual patient rather than the treatment regimen. These included documentation by providers of patient preference, such as declining treatment because of planned travel back to their home country, or anxiety about accepting treatments because of past experiences; financial issues that precluded care; missed appointments for unclear reasons; and extended time between diagnosis at an outside hospital and presentation for care at our institution. In part, these reasons exemplify the social determinants of health, or the environmental conditions in which people live that affect a wide array of health, functioning, and life outcomes.²⁴ These examples help demonstrate complexities in treating an underserved, ethnically diverse population, and highlight the need for innovative solutions.

Whether attributable to the complexities of treatment or individual patient characteristics, the reasons identified for delay in this study are potentially modifiable. Improvements to

care delivery start with a robust monitoring system, like the CP³R, which prompted this study. Health system interventions that maximize coordination of multidisciplinary care are necessary to address determinants of quality treatment.²⁵ For example, one study pilot tested a program for medical oncologists to create a breast cancer treatment plan to distribute to patients and other care providers.²⁶ A treatment plan could be incorporated into the EMR to improve visibility and awareness among providers and meet meaningful use criteria.²⁷ Another opportunity for system improvement is using patient navigation programs, which target individual barriers to care such as those demonstrated here. These navigation programs, now a CoC requirement,¹³ are gaining popularity as one way of addressing these obstacles to care.²⁸⁻³⁰ However, data are lacking to document the ability of such programs to address the barriers specific to the unique needs of the population or their effects on quality cancer care delivery.^{31,32} At our institution, breast cancer patient navigators are now used to help address these social and health system obstacles. Through a systematic assessment of barriers specific to the individual patient, the navigator works with the multidisciplinary care team to address obstacles that interfere with care delivery. For example, if travel is planned outside the country, the navigator notifies all care providers, contacts family members to engage them in decision making, and refers the patient to a social worker to help organize treatment plans.

Limitations of our study include the small sample size drawn from a single institution. However, our institution exemplifies care at urban safety net settings across the country that serve our most vulnerable populations. The qualitative methods used to create our reasons for delay categories are not standardized; rather, they are reflective of the cases seen at our institution. Although we cannot demonstrate that the reasons we identified are the root cause for delays in treatment, study findings demonstrate high-impact areas in which to intervene. We did not have access to outside medical records to determine whether patients ever received care elsewhere, but previous work demonstrates that the majority of patients in our population seek long-term care within the safety net system, supporting the likelihood that we captured most of their treatment history.³³

We found complex reasons for noncompliance with the NQF quality metric for HT in breast cancer treatment at our safety net hospital, many of which are modifiable. Effective interventions are urgently needed to reduce the pervasive breast cancer treatment disparities in this population and should take into account both complex cancer treatment regimens as well as social determinants of health. Understanding the needs of vulnerable patients within an increasingly complex health care system is critically important to our ability to provide high-quality and equitable care for all patients.

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Author Contributions

Conception and design: Meaghan M. Crowley, Tracy A. Battaglia

Administrative support: Tracy A. Battaglia

Collection and assembly of data: Meaghan M. Crowley, Molly E. McCoy, Sharon M. Bak, Sarah E. Caron, Faber Alvis

Data analysis and interpretation: Meaghan M. Crowley, Molly E. McCoy, Sharon M. Bak, Naomi Ko, Lisa A. Kachnic, Faber Alvis, Tracy A. Battaglia

Manuscript writing: All authors

Final approval of manuscript: All authors

Corresponding author: Tracy A. Battaglia, MD, MPH, 801 Massachusetts Ave Crosstown Center, Women's Health Unit, 1st Floor, Boston, MA 02118; e-mail: Tracy.battaglia@bmc.org.

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