High Initiation of Adjuvant Hormonal Therapy Among Uninsured Stages I–III Breast Cancer Patients Treated in a Safety-Net Healthcare System

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Abstract

Objective: Despite benefits of adjuvant hormonal therapy (AHT), many eligible breast cancer patients do not complete therapy as recommended. Patterns of AHT use have not been well studied among uninsured breast cancer patients who fall into coverage gaps or are ineligible for public insurance programs.

Methods: We identified 291 patients newly diagnosed with stages I–III hormone receptor-positive breast cancer from January 2008 to December 2012. All patients were treated at a safety-net healthcare system and enrolled in an income-based medical assistance program that fills AHT prescriptions at low cost. We extracted and linked cancer registry, pharmacy claims, and medical record data to assess AHT initiation (defined as a new AHT prescription ≤ 18 months since diagnosis) and sociodemographic and healthcare utilization variables. Log-binomial regression was used to identify correlates of initiation.

Results: Overall, 239 (82%) patients initiated AHT. Tamoxifen (42%) and anastrozole (55%) were most commonly prescribed. The mean copay was \$4.90 for tamoxifen and \$6.00 for anastrozole. Although crude analyses revealed small, statistically significant prevalence ratios for race/ethnicity (Hispanic vs. white, other vs. white), year of diagnosis (2008 vs. 2012), primary care visit before diagnosis (any vs. none), and smoking status (current vs. never), there were no significant correlates of initiation in the adjusted model.

Conclusion: Safety-net healthcare systems providing access to AHT (*i.e.*, through reduced copays) could improve the number of eligible patients initiating therapy. Continuity and integration of care in these settings may reduce disparities frequently observed in uninsured, low-income breast cancer populations.

Keywords: breast cancer, adjuvant hormonal therapy, medication adherence

Introduction

ADJUVANT HORMONAL THERAPY (AHT) is widely considered a critical component of breast cancer care because it improves long-term survival of patients with hormone receptor-positive (HR+) disease. Treatment guidelines recommend at least 5—and up to 10—years of tamoxifen and/or aromatase inhibitors.¹

Patterns of AHT use (including initiation, adherence, and persistence) have been extensively studied in Medicaid,

Medicare, and privately insured populations.^{2,3} Over half of eligible patients in these studies do not complete treatment as recommended.² However, AHT use in under- and uninsured populations is unknown. This is particularly concerning in light of the large number of states opting out of Medicaid expansion through the Affordable Care Act. An estimated 3 million adults in nonexpansion states fall into a “coverage gap.”⁴ These individuals mostly live in states with an existing large, uninsured population not eligible for Medicaid (*e.g.*, undocumented, noncitizens). Safety-net systems caring

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for uninsured and low-income populations will be an important source of care for those who remain uninsured in states not implementing Medicaid expansion.⁵

At the same time, greater efforts are being made to evaluate cancer care delivered in community settings, where more than 80% of cancer patients are treated. Rapidly evolving healthcare systems (payment reform, new models of care delivery, outcome measurement) call for a better understanding of how cancer care is delivered in diverse settings and the patient- and system-level factors influencing health outcomes.⁶

Growing interest in both AHT and cancer care delivery highlights an important gap in the literature regarding variations in AHT use across diverse, multipayer populations. Specifically, little is known about AHT use in uninsured breast cancer patients who fall into coverage gaps or ineligible for public insurance programs. We examined prevalence and correlates of AHT initiation among newly diagnosed, uninsured breast cancer patients treated at a large, urban safety-net healthcare system.

Materials and Methods

Study population

This study was conducted at Parkland Health & Hospital System (Parkland), the safety-net healthcare system for Dallas County, TX. Parkland is a vertically integrated system that includes 12 community-based primary care clinics, a multidisciplinary breast cancer clinic, inpatient hospital, and outpatient pharmacy. Parkland cares for large numbers of poor, under- or uninsured patients with a comprehensive electronic medical record (EMR; EpicCare, Verona, WI).

We identified all women (age ≥ 21 years) in the hospital cancer registry with an incident diagnosis of stages I–III HR+ breast cancer between January 2008 and December 2012 (Fig. 1; $n=699$). We limited the study population to uninsured patients who were not eligible for public insurance (e.g., Medicaid) and were enrolled in a medical assistance program for Dallas County residents ($n=368$). The program is funded by county tax payers, private donations, and grants; eligibility is based on household income (gross monthly

FIG. 1. Study flow diagram. HR+, hormone receptor positive.

TABLE 1. CHARACTERISTICS OF 291 STAGES I–III HORMONE RECEPTOR-POSITIVE BREAST CANCER SURVIVORS ENROLLED IN MEDICAL ASSISTANCE PROGRAM AND TREATED AT PARKLAND HEALTH & HOSPITAL SYSTEM BY INITIATION OF ADJUVANT HORMONAL THERAPY, JANUARY 2008–DECEMBER 2012

	Initiator (n= 239)		Noninitiator (n= 52)		
	n	%	n	%	p
Sociodemographic characteristics					
Age at diagnosis					0.65
Mean (SD)	53.0	(10.08)	52.3	(11.34)	
Median (range)	53.3	(28–83)	51.4	(27–85)	
Race/ethnicity					0.03
NH white	29	12.1	14	26.9	
NH black	79	33.5	19	36.5	
Hispanic	108	45.2	16	30.8	
Other	23	9.6	3	5.8	
Marital status					0.08
Married/living with partner	75	31.4	23	44.2	
Not married	164	68.6	29	55.8	
Menopausal status ^a					0.19
Premenopausal	82	34.3	23	44.2	
Postmenopausal	157	65.7	29	55.8	
Family history of breast cancer					0.30
No	156	69.6	40	76.9	
Yes	68	30.4	12	23.1	
Missing	15				
Tumor/treatment characteristics					
Year of diagnosis					0.23
2008	36	15.1	2	3.9	
2009	49	20.5	13	25.0	
2010	49	20.5	10	19.2	
2011	50	20.9	10	19.2	
2012	55	23.0	17	32.7	
Cancer stage ^b					0.58
I	80	33.5	24	41.2	
II	101	42.3	16	37.3	
III	58	24.3	10	21.6	
Missing	0		1		
Histologic grade					0.42
Well/moderately differentiated	170	72.3	34	66.7	
Poorly/undifferentiated	65	27.7	17	33.3	
Missing	4		1		
Received chemotherapy					0.43
No	79	33.5	20	39.2	
Yes	157	66.5	31	60.8	
Missing	3		1		
Received radiation					0.06
No	58	24.8	19	38.0	
Yes	176	75.2	31	62.0	
Missing	5		2		
Type of therapy initiated					
Tamoxifen	101	42.3			
Anastrozole	132	55.2			
Letrozole	5	2.1			
Exemestane	1	0.4			
Health history					
Tobacco use					<0.001
Current	38	16.7	17	35.4	
Former	22	9.7	9	18.8	
Never	168	73.7	22	45.8	
Missing	11		4		
Primary care at Parkland					0.02
No	84	35.2	27	51.9	
Yes	155	64.9	25	48.1	

(continued)

TABLE 1. (CONTINUED)

	Initiator (n = 239)		Noninitiator (n = 52)		p
	n	%	n	%	
Comorbid conditions ^c					0.37
0	62	26.2	17	32.7	
1	56	23.6	8	15.4	
≥2	119	50.2	27	51.9	
Missing	2				
Mental illness ^c					0.75
No	201	84.5	43	82.7	
Yes	37	15.6	9	17.3	
Missing	1				
Illicit drug use ^c					0.99
No	218	94.4	48	94.1	
Yes	13	5.6	3	5.9	
Missing	8		1		
No. of other prescription medications ^{c,d}					0.39
Mean (SD)	5.1 (3.96)		4.6 (3.03)		
Median (range)	4.0 (0–20)		4.0 (0–11)		

Menopausal status, family history of breast cancer, comorbid conditions, mental illness, illicit drug use, and number of other prescription medications abstracted from patient medical record; all other variables reported in Parkland Cancer Registry.

Gray shading indicates type of therapy initiated.

^aPatients with missing menopausal status ($n=7$) were reclassified based on age and type of adjuvant hormonal therapy initiated.

^bHighest clinical or pathological stage reported.

^cMeasured at the completion of active treatment (*i.e.*, some combination of surgery, radiation, and chemotherapy).

^dOther prescription medications may include over the counter medications (*e.g.*, ibuprofen).

income at or below 200% federal poverty level). Enrolled patients receive health benefits, including primary and specialty care, hospitalizations, and prescription drug coverage. Prescriptions dispensed by Parkland outpatient pharmacies are provided for free or at a reduced price. Coverage does not extend to commercial pharmacies; thus, most patients fill prescriptions at Parkland. We further excluded patients who did not undergo cancer-directed surgery ($n=19$), received primary cancer treatment outside of Parkland ($n=25$), were previously treated with AHT (*i.e.*, as chemoprevention) ($n=17$), or were diagnosed with a synchronous cancer ($n=16$).

Data sources and covariates

We extracted and linked pharmacy claims, hospital cancer registry, and EMR data to assess AHT initiation. Initiation was defined as a new prescription claim for AHT within 18 months of diagnosis.

Tamoxifen, anastrozole, letrozole, and exemestane prescriptions from January 2008 to July 2014 were electronically queried from Cerner (Kansas City, MO), a prescription claims database linked to the EMR. Pharmacy data included prescription dates, day's supply, retail cost, and patient co-payment amount.

Sociodemographic and tumor/treatment information, including age at diagnosis, race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, other), marital status (married/living with partner, not married), stage at diagnosis, histologic grade, receipt of chemotherapy, and receipt of radiation therapy, was derived from the hospital cancer registry. Stage at diagnosis reflects the farthest extent of disease based on the combined clinical and pathological assessment according to the American Joint Committee on Cancer staging manual, sixth edition.

Two trained research assistants manually abstracted the EMR for information on patient health history at the time of diagnosis. Variables included menopausal status (pre-, post-menopausal), family history of breast cancer (first-degree relative), tobacco use (current, former, never smoker), receipt of primary care at Parkland (*i.e.*, ≥1 primary care outpatient visit before diagnosis), comorbidity, history of mental illness, history of illicit drug use, and number of other prescription medications. Comorbidity was measured as none, one, or two or more of the following conditions: asthma, coronary artery disease, diabetes, hyperlipidemia, hypertension, and peripheral vascular disease. Mental illness and illicit drug use were documented in the problem list and clinic notes by providers. For quality assurance purposes, both research assistants collected data on a random 10% sample. Discrepancies were adjudicated until consensus was reached.

Statistical analyses

Descriptive statistics (*e.g.*, frequencies, proportions, and means) were used to examine characteristics of the study population by AHT initiation. Pearson's chi-square or Fisher's exact tests were used to compare categorical characteristics of initiators and noninitiators, and *t*-tests were used to compare continuous characteristics (*e.g.*, age at diagnosis).

Log-binomial regression analysis was used to identify potential correlates of initiation. We included patient age at diagnosis and race/ethnicity as *a priori* correlates of initiation. Other covariates were included in the multivariable model if they were significantly associated with AHT initiation in the bivariate analysis ($p<0.20$, see Table 1) and were not highly correlated (Pearson's $r<0.50$) with one another (*e.g.*, age at diagnosis and menopausal status). Using these criteria, we selected the following covariates: age at diagnosis, race/ethnicity, marital status, receipt of radiation

therapy, tobacco use, receipt of primary care at Parkland, and comorbidity. Unadjusted and adjusted associations of covariates and AHT initiation are reported as prevalence ratios (PRs) and 95% confidence intervals (CIs). All statistical analyses were conducted using SAS version 9.3 (SAS Institute, Cary, NC).

Results

Characteristics of the study population ($n = 291$) are shown in Table 1. Most patients were Hispanic (42.6%), not married (66.3%), and postmenopausal (63.9%), with no family history of breast cancer (71.0%). Mean age was 52.9 years (range 27–85). The majority had one or more comorbid conditions (72.2%), and the most prevalent comorbidities were hypertension (51.2%), hyperlipidemia (25.1%), and diabetes (20.3%).

Overall, 239 (82.1%) breast cancer patients initiated AHT within 18 months of diagnosis (Table 1). Tamoxifen (42.3%) and anastrozole (55.2%) were most commonly prescribed. Patients initiated AHT within a mean of 8.3 months since diagnosis (Fig. 2). Mean retail price of tamoxifen and anastrozole was \$126.80 and \$472.20, respectively, with a mean copay of \$4.90 for tamoxifen and \$6.00 for anastrozole. Type of AHT initiated in each study year and the cost did not vary substantially over time (not shown).

In unadjusted analysis (Table 2), patients who were Hispanic (PR 1.29, 95% CI 1.04–1.61) and other (PR 1.31, 95% CI 1.02–1.68) race/ethnicity, diagnosed in year 2008 (vs. 2012, PR 1.24, 95% CI 1.07–1.44), and received primary care at Parkland before diagnosis (PR 1.14, 95% CI 1.01–1.28) were more likely to initiate AHT. Current smokers (vs. never, PR 0.78, 95% CI 0.65–0.94) were less likely to initiate AHT. No variables remained statistically significant in the adjusted model (Table 2). Results were similar in reduced models that removed select covariates (Supplementary Table S1; Supplementary Data are available online at www.liebertpub.com/jwh).

Discussion

The high proportion (82%) of breast cancer patients initiating AHT in our study provides some preliminary evidence that continuity of care in integrated safety-net healthcare systems may reduce disparities in uninsured communities. Initiation was higher in our study population than in Medicare- or Medicaid-insured patients, where prevalence of initiation ranges from 50% to 85%.^{7–15} Time to initiation was also prompt, with 70% initiation within the first 12 months after diagnosis. Our results provide a more complete picture of variations in AHT use across multipayer populations.

Racial disparities in AHT use have been frequently observed,³ but we found no differences in initiation by race/ethnicity. A recent study¹² that examined whether black and Hispanic women who participated in the Women's Health Initiative were less likely than white women to report using AHT similarly found no difference in prevalence of initiation by race/ethnicity. However, some research in this area^{7,9,10} suggests there are racial differences in AHT initiation and adherence, and a lower proportion of black patients receive therapy compared to whites. AHT initiation in other safety-net healthcare systems is low,⁹ where black, Hispanic, and foreign-born breast cancer patients are less likely to initiate therapy. Across these studies, there may be important differences in healthcare systems' organizational structure and care delivery that contribute to mixed findings concerning racial differences in AHT use. Specifically, the integrated design of the healthcare system at Parkland (including a multidisciplinary breast oncology clinic and centralized pharmacy) likely facilitates more comprehensive and coordinated monitoring of cancer care and follow-up during and after active treatment (*i.e.*, completion of surgery, radiation, and/or chemotherapy). This is consistent with our finding that patients who received outpatient primary care at Parkland before diagnosis were more likely to initiate AHT than patients with no previous interaction with the healthcare system, although it was not statistically significant in the adjusted analysis. Care coordination in integrated settings may play a bigger role in receipt of therapy than

FIG. 2. Time since diagnosis (in days) to initiation of adjuvant hormonal therapy among 239 stages I–III hormone receptor-positive breast cancer survivors. AHT, adjuvant hormonal therapy.

TABLE 2. LOG-BINOMIAL REGRESSION MODEL^a OF FACTORS ASSOCIATED WITH INITIATION OF ADJUVANT HORMONAL THERAPY AMONG 291 STAGES I–III HORMONE RECEPTOR-POSITIVE BREAST CANCER SURVIVORS

	Unadjusted PR (95% CI), n=291	Adjusted ^b PR (95% CI), n=267 ^c
Age at diagnosis	1.00 (1.00–1.01)	1.00 (0.99–1.00)
Race/ethnicity		
NH white	1.00	1.00
NH black	1.20 (0.95–1.50)	1.03 (0.89–1.20)
Hispanic	1.29 (1.04–1.61)	1.09 (0.90–1.31)
Other	1.31 (1.02–1.68)	1.10 (0.83–1.46)
Marital status		
Married/living with partner	1.00	1.00
Not married	1.11 (0.98–1.26)	1.08 (0.94–1.24)
Received radiation		
No	1.00	1.00
Yes	1.13 (0.98–1.30)	1.03 (0.91–1.16)
Tobacco use		
Current	0.78 (0.65–0.94)	0.94 (0.81–1.08)
Former	0.80 (0.64–1.01)	0.93 (0.80–1.09)
Never	1.00	1.00
Primary care at Parkland		
No	1.00	1.00
Yes	1.14 (1.01–1.28)	1.05 (0.92–1.18)
Comorbid conditions		
0	1.00	1.00
1	1.11 (0.96–1.29)	1.07 (0.89–1.30)
≥2	1.04 (0.90–1.19)	1.06 (0.89–1.26)

^aPatient age at diagnosis and race/ethnicity were included as *a priori* correlates of initiation. Other covariates were included in the multivariable model if they were significantly associated with adjuvant hormonal therapy initiation in the bivariate analysis ($p < 0.20$, see Table 1) and were not highly correlated with one another (Pearson's $r < 0.50$). Age at diagnosis and menopausal status were the only highly correlated variables. Because age was included *a priori* in the multivariable model, we did not include menopausal status.

^bAdjusted for all variables listed in table.

^cObservations with missing data on radiation receipt ($n = 7$), tobacco use ($n = 15$), and comorbid conditions ($n = 2$) were excluded from the adjusted analysis ($n = 24$ total).

CI, confidence interval; PR, prevalence ratio.

patient characteristics such as race/ethnicity. It will be important to monitor how provider- and system-level factors contribute to adherence and persistence, especially as healthcare policies and organizations continue to evolve.

Reduced copays available to Parkland patients may have also contributed to higher AHT initiation. Cost plays an important role in treatment decisions, and cancer patients who experience financial problems are more likely to delay or forgo care.¹⁶ Costs related to AHT may explain the prevalence of nonadherence observed in many studies,^{17–19} but our results provide some evidence that removing access barriers, such as high out-of-pocket costs, may promote timely receipt of therapy. In our study, the average retail price of anastrozole was greater than \$400 for a 30-day supply. Patients enrolled in the medical assistance program, however, only paid a small portion (\$5–6) of this cost, comparable to generic medications at big box retailers. Simulation modeling suggests that providing full prescription coverage (vs. usual coverage) for aromatase inhibitors to Medicare beneficiaries results in greater quality-adjusted life years and less resource use per beneficiary.¹⁸ A different study¹⁹ showed that breast cancer patients with prescription drug coverage were more than twice as likely to initiate and continue AHT as patients without coverage. Collectively, these results illustrate how reducing or eliminating cost sharing for essential drugs could be an effective strategy for enhancing receipt of guideline-recommended care.

Electronic prescription orders were implemented in the middle of the study period, which limited our ability to assess physician prescription practices. We could not distinguish between patients who were recommended but did not fill a prescription for AHT (*i.e.*, patient nonadherence) and patients who were never recommended or prescribed AHT (*i.e.*, physician nonadherence). We noted that the proportion of patients who received an electronic prescription order for AHT increased over time, from 32% in 2008 to 100% in 2012, suggesting that clinical information systems facilitating electronic prescribing may also be an important system-level factor related to care quality. Patients included in our study received prescriptions at Parkland for free or a reduced price, and coverage does not extend to commercial pharmacies. However, patients could have filled an AHT prescription at a pharmacy other than Parkland (*e.g.*, Walgreens, Target), which was not captured in the data. Although the prohibitive costs of AHT, particularly for aromatase inhibitors,¹⁸ make it unlikely that patients would fill prescriptions elsewhere, initiation prevalence may be slightly underestimated.

Conclusions

Our findings have policy implications for healthcare systems caring for uninsured populations: integrated systems with payer programs providing access to AHT (*i.e.*, through reduced prescription copays) could improve the number of

eligible patients initiating therapy. Given recent recommendations for longer duration of AHT¹ and shift from infusion to oral chemotherapies,^{20,21} it is especially important to understand how pharmacy benefits and other multi-level factors influence completion of the AHT regimen (*e.g.*, adherence, persistence) beyond initiation.

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Author Disclosure Statement

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