

Time to Diagnostic Evaluation After Mammographic Screening in an Urban Setting

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Abstract

Background: The Capital Breast Care Center (CBCC), a screening facility established to serve minority women, developed a culturally sensitive patient care paradigm that would address concerns of adherence to follow-up of abnormal results after initial mammogram. Women with abnormal mammograms are assigned a Black or Latina navigator who facilitates the additional workup needed by scheduling follow-up, arranging transportation, providing counsel/emotional support, and even accompanying them to diagnostic imaging or biopsy appointment. We present data on follow-up rates after breast cancer screening.

Methods: All patients seen at CBCC are entered into a prospectively collected database. We calculated intervals (in days) between the screening and diagnostic visits. Descriptive statistics and median time to follow-up are reported. Differences between Black and Hispanic women on time interval were tested by *t*-test.

Results: From January 2010 to December 2012, 4605 digital screening mammograms were performed. Fifty-two percent of the women self-identified as Black, 41% as Hispanic, 4% White, 2% Asian, and 1% as “other.” Of the screening studies, 451 (9.8%) required additional workup, out of which 362 (80%) of the women returned for the recommended diagnostic imaging. The median interval between screening and diagnostic imaging was 39 days (range: 6–400). Of the 162 women recommended to have a core needle biopsy, 81.5% underwent biopsy within a median of 21 days (range: 0–221 days).

Conclusion: At the CBCC, time to patient follow-up after initial mammographic screening is within the CDC-recommended performance standard of less than 60 days. For a population that historically has low rates of clinical follow-up, we attribute this reduction in delays to breast cancer diagnostic resolution to a culturally sensitive patient navigation program. Additional studies are needed to assess how the existing navigation program can be individualized/tailored to target the remaining 20% of women who did not adhere to the recommended workup.

Keywords: breast cancer, screening mammography, patient navigation, diagnostic, minority health

Introduction

CANCER PATIENT NAVIGATION IS a strategy designed to reduce delays in accessing cancer care services from screening through diagnosis and treatment.¹ Research suggests that barriers to healthcare access result in underutilization of breast cancer screening, leading to delay in diagnosis and treatment.^{2–4} The term “patient navigation” was coined by Dr. Harold Freeman in the 1990s after the first program was established in Harlem, New York.⁵ Since then, many programs have been established throughout the country to address barriers to obtaining cancer care in underserved populations.^{6–9} Various navigation models and interventions

have been described with care provided by professionals and lay persons of various levels of training.¹ Patient navigation can potentially impact cancer care across the entire continuum: screening, diagnosis, initiation of treatment, treatment adherence and completion, survivorship, and end-of-life care.⁵

The reported efficacy of patient navigation programs in improving the adherence to follow-up visits after a screening abnormality has ranged in the literature from 21% to 29%.¹ In a review of 17 cancer patient navigation efficacy studies, Wells et al. reported that the strongest evidence to date for the effectiveness of patient navigation lies in the improvements in cancer screening.¹⁰ Few studies have been published on the effect of patient navigation on diagnostic resolution,

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treatment outcomes, survivorship, and end of life.¹¹ In four randomized trials,^{12–14} three found a benefit with patient navigation for women undergoing breast cancer screening, as time to resolution was significantly shorter in the navigated group. Wells et al., however, concluded that patient navigation did not impact the overall time to completion of diagnostic studies or the number of patients who reached diagnostic resolution of a cancer abnormality.¹³

CBCC was established to address mammography underutilization among minority (Black and Hispanic) women in the Washington, DC metro area. Recognizing that having women come in for screening is just the beginning and further efforts are needed to encourage any subsequent workup, navigators were employed. Integral to CBCC's patient care algorithm is the culturally sensitive patient navigation services provided for women who require further workup after initial breast cancer screening. All women with abnormal imaging are assigned a navigator who facilitates the additional workup needed by coordinating subsequent appointments, arranging transportation, providing counseling/emotional support, and helping those who are eligible obtain insurance.

While the current literature supports the theory that navigation increases initial screening rates, little has been published that quantifies the effect on time to follow-up of abnormal imaging. This is complicated by a lack of consensus as to what a reasonable follow-up interval should be after an abnormal mammogram.¹⁵ No formal recommendations are available on the recommended time from screening to diagnostic imaging to biopsy. The CDC, through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), set predefined quality standards of establishing a diagnosis within 60 days of an abnormal screening test result.^{16–18} We analyze our prospectively collected data on time from screening to diagnostic workup at CBCC to evaluate whether our navigation-based services achieve this benchmark.

Methods

The CBCC was founded in 2004 as a community initiative of Georgetown University's Lombardi Comprehensive Cancer Center with foundation support from Avon. The center is currently part of Georgetown University's Minority Health and Health Disparities Program. From inception, the goal has been to provide medically underserved women with accessible breast health information and screening at a community-based, accredited mammography facility in Washington, DC. Over the past 8 years, the Center has screened and evaluated more than 9000 women for breast cancer. Nearly 20% of women screened for breast cancer receive abnormal findings with abnormal mammogram and/or abnormal clinical breast exams.

Patient visits are conducted with a brief interview to acquire demographic information. Women then have a clinical breast examination by an experienced provider who also provides instruction on breast health, abnormal conditions, and when to contact a medical professional. Those within screening age (40 or older) proceed to imaging. We present data on women who require diagnostic imaging after a screening mammogram. Those with a subjective breast complaint or who have a palpable abnormality on examination are excluded from analysis.

Women who require additional workup are assigned a patient navigator, who facilitates the diagnostic evaluation with further imaging or biopsies. There are two navigators and they reflect the population serviced by CBCC, black and Hispanic, with one being a fluent Spanish speaker. The navigators also may accompany the patient for the additional required appointments. Our navigation services are evaluated based on the performance measure of number of days between screening and completion of workup. For those who ultimately are diagnosed with cancer, we evaluate time from screening to diagnosis.

Since January 2010, all patients presenting for screening have their information prospectively collected and entered into the electronic medical record (EMR) system. Variables collected include demographic data (age, race, ethnicity, education level, and ward of residence), insurance status, and the date of the first abnormal screening with the subsequent diagnostic workup. These data were abstracted from January 2010 to December 2012 with approval from the Institutional Review Board at Georgetown University.

Statistical methods

We calculated the time intervals (in days) between the screening and diagnostic visits. Descriptive statistics and median time to follow-up are reported as the primary outcomes of interest. Differences between groups on time interval were tested by the *t*-test. Univariate comparisons between groups were performed using the log-rank test. A *p*-value ≤ 0.05 was considered significant. We also conducted multivariate analysis using a Cox proportional hazards model that included age, race, education, and insurance status as predictors of time to follow-up testing. All statistical analyses were conducted in SAS version 9.3.

Results

From January 2010 to December 2012, 4605 digital screening mammograms were performed with 3174 (68.9%) of these being first-time screening examinations. The median age of the study population was 53 years (range 35–91) with 52% of the women self-identifying as Black, 41% as Hispanic, 4% White, 2% Asian, and 1% as "other." Seventy percent of the woman reported completing high school or higher and 53% were uninsured.

Table 1 shows the outcomes of the screening studies: 451 (9.8%) of the imaging tests required additional workup and were designated a Breast Imaging-Reporting and Data System (BI-RADS) 0. Of the women requiring additional imaging, 362 (80%) returned for the recommended follow-up

TABLE 1. OUTCOMES OF SCREENING MAMMOGRAMS AT THE CAPITAL BREAST CARE CENTER (N=4605)

Impression (reported BI-RADS)	n	%
0. Needs additional evaluation	451	10
1. (negative)	2682	58
2. (benign finding—negative)	1408	31
3. (probably benign—short-term interval follow-up)	52	1
4. (low suspicion of abnormality)	2	<1

BI-RADS, Breast Imaging Reporting and Data System.

appointment for diagnostic evaluation (Table 2). The median interval between screening and diagnostic imaging was 39 (range 6–400 days). Twenty-nine percent followed up in ≤30 days and 64% returned for follow-up in ≤60 days. Seventy-eight percent of African American women received follow-up diagnostic imaging, while 85% of Hispanic women returned (no significant difference in receipt of follow-up imaging between racial groups, insurance status, or education). On diagnostic imaging, 133 (11%) had a BI-RADS 4 and 21 (2%) received a BI-RADS 5.

Of those with abnormal imaging, 162 out of 451 (35.9%) were recommended to have a biopsy. Among the women who were recommended to have a core needle biopsy after the diagnostic screening, 132 (81.5%) underwent biopsy within a median of 21 days (interquartile range: 0–221 days) (Table 3). Overall, there were 5 high-risk lesions (atypia) and 19 invasive and intraductal breast cancers (1.9 cancers/1000) diagnosed in the 3-year period. African American women received biopsies within 17 days, while Hispanic women obtained biopsies within 31 days. Spanish speaking women returned for biopsies within 37 days compared to 18 days in English speakers. There was no difference in days to biopsies in women with less than high school education compared to those with graduate or higher education. Although not to statistical significance, there was a difference in days to biopsy based on insurance status, categorized as government, private, or uninsured (Table 3). Women with government insurance had the longest time to

biopsy of 26 days compared to 14 days for those with private insurance and 17 days for the uninsured.

In multivariate analysis (Table 4), there is no association between age, race, education, or insurance status with receipt of diagnostic imaging after an abnormal screening mammogram or receipt of biopsy after a biopsy recommendation.

Discussion

We report our experience at the CBCC over a 3-year period (2010–2012). During the study period, over 4000 screening studies were performed in a population that is majority Black/African American and Hispanic. This study depicts the outcomes of the ~10% of women who required additional workup after screening mammography. We found a follow-up rate of 80% after which diagnostic imaging and biopsies were obtained using a patient navigation model. In nonrandomized, but prospective trials, results also support the use of patient navigation.^{19,20} In a cohort of 437 African American women, Clark reported timely follow-up after abnormal results from screening mammograms in 85% of the study participants.¹⁹ Also, in a Chicago-based cancer patient navigation program with 352 women with breast abnormalities, compared to controls, the breast navigation group had shorter time to diagnostic resolution (adjusted HR = 1.65, confidence interval = 1.20–2.28).²⁰ Hoffman et al. included patients from CBCC in their analysis of 2601 women of which 1047 received patient

TABLE 2. FOLLOW-UP AFTER SCREENING MAMMOGRAPHY

	<i>Requiring additional evaluation (n)</i>	<i>Received follow-up diagnostic imaging, n (%)</i>	<i>Time to follow-up (in days), median (range)</i>	<i>Follow-up time ≤30 days, n (%)</i>	<i>Follow-up time ≤60 days, n (%)</i>
All patients	451	387 (86)	40 (6–400)	136 (30)	309 (69)
Age					
40–49	187	162 (87)	38 (7–400)	62 (33)	127 (68)
50–64	234	199 (85)	41 (6–361)	59 (25)	151 (65)
≥65	30	26 (87)	41 (9–170)	10 (33)	20 (67)
<i>p</i> -Value		0.90	0.42	0.20	0.85
Race					
African American/Black	201	169 (84)	37 (6–276)	60 (30)	130 (65)
Hispanic	194	177 (91)	42 (11–400)	47 (24)	134 (69)
White	17	13 (76)	22 (9–94)	9 (53)	11 (65)
Asian	11	8 (73)	30 (22–89)	4 (36)	7 (64)
<i>p</i> -Value		0.90	0.03	0.01	0.74
Education					
Less than high school	113	97 (86)	47 (11–400)	20 (18)	72 (64)
High school or GED	108	92 (85)	41 (7–243)	30 (28)	70 (65)
College or trade school	152	132 (87)	35 (6–361)	51 (34)	106 (70)
Graduate or higher	18	16 (89)	25 (9–220)	9 (64)	13 (72)
<i>p</i> -Value		0.73	<0.01	<0.01	0.70
Language					
English	254	208 (82)	35 (6–276)	83 (33)	165 (65)
Spanish	197	179 (91)	43 (11–400)	48 (24)	133 (68)
<i>p</i> -Value		0.24	<0.01	<0.01	0.24
Insurance					
Government	347	298 (86)	40 (6–361)	96 (28)	227 (65)
Private	40	36 (90)	33 (10–139)	16 (40)	31 (78)
Uninsured	63	53 (84)	40 (11–400)	19 (30)	40 (63)
<i>p</i> -Value		0.75	0.16	0.32	0.39

GED, General Education Diploma.

TABLE 3. FOLLOW-UP OF BIOPSY RECOMMENDATION AFTER DIAGNOSTIC IMAGING

	<i>Biopsy recommended (n)</i>	<i>Received biopsy, n (%)</i>	<i>Time to biopsy (in days), median (range)</i>	<i>Follow-up time ≤14 days, n (%)</i>	<i>Follow-up time ≤30 days, n (%)</i>
All patients	152	128 (84)	21 (1–221)	45 (35)	77 (60)
Age					
40–49	61	55 (90)	23 (3–221)	21 (34)	33 (54)
50–64	77	60 (78)	28 (4–116)	19 (25)	34 (44)
≥65	14	13 (93)	15 (8–89)	5 (36)	10 (71)
<i>p</i> -Value		0.10	0.50	0.74	0.40
Race					
African American/Black	80	72 (90)	18 (3–116)	31 (39)	50 (63)
Hispanic	50	37 (74)	34 (1–221)	7 (14)	18 (36)
White	7	6 (86)	18 (8–88)	3 (43)	4 (57)
Asian	5	5 (100)	50 (10–60)	1 (20)	1 (20)
<i>p</i> -Value		0.11	<0.01	0.08	0.03
Education					
Less than high school	36	26 (72)	16 (1–93)	11 (31)	19 (53)
High school or GED	30	28 (93)	21 (7–100)	8 (27)	18 (60)
College or trade school	51	47 (92)	28 (3–161)	15 (29)	25 (49)
Graduate or higher	12	7 (58)	16 (5–99)	3 (25)	5 (42)
<i>p</i> -Value		<0.01	0.75	0.68	0.36
Language					
English	103	93 (90)	19 (3–116)	40 (39)	63 (61)
Spanish	49	35 (71)	37 (1–221)	5 (10)	14 (29)
<i>p</i> -Value		<0.01	<0.01	<0.01	<0.01
Insurance					
Government	126	106 (84)	26 (1–221)	35 (28)	61 (48)
Private	18	17 (94)	14 (5–83)	8 (44)	12 (67)
Uninsured	8	5 (63)	17 (7–56)	2 (25)	4 (50)
<i>p</i> -Value		0.12	0.30	0.52	0.39

navigation in Washington, DC and reported a positive impact on delays in breast cancer diagnosis.¹²

Within our cohort, there are no differences in the receipt of additional imaging based on race, education, or insurance status. However, there is a difference between black and

Hispanic women in the receipt of recommend biopsies. African American women received biopsies within 17 versus 31 days in Hispanics. This delay to biopsy in Hispanic women deserves further investigation. There is limited, but emerging data focusing specifically on screening behaviors

TABLE 4. FACTORS ASSOCIATED WITH RECEIPT OF DIAGNOSTIC IMAGING AFTER AN ABNORMAL SCREENING MAMMOGRAM AND BIOPSY AFTER A BIOPSY RECOMMENDATION IN MULTIVARIABLE SURVIVAL ANALYSIS MODELS

	<i>Diagnostic imaging</i>		<i>Biopsy</i>	
	<i>Hazard ratio^a</i>	<i>95% confidence interval</i>	<i>Hazard ratio^a</i>	<i>95% confidence interval</i>
Age ^b	0.91	0.79, 1.05	0.96	0.80, 1.15
Race				
African American/Black	Ref		Ref	
Hispanic	1.17	0.92, 1.50	0.45	0.29, 0.70
White	0.76	0.41, 1.39	0.73	0.28, 1.86
Asian	0.90	0.44, 1.83	0.89	0.38, 2.09
Education				
Less than high school	Ref		Ref	
High school or GED	1.08	0.80, 1.47	1.23	0.70, 2.14
College or trade school	1.25	0.94, 1.65	0.98	0.58, 1.67
Graduate or higher	1.52	0.85, 2.72	0.42	0.18, 1.10
Insurance				
Private	Ref		Ref	
Government	0.76	0.50, 1.16	0.60	0.33, 1.08
Uninsured	0.68	0.40, 1.15	0.67	0.25, 1.82

^aAdjusting for other variables in the table.

^bHazard ratios based on a 10 year increase in age.

and diagnostic resolution in Hispanic women. Ramirez et al. in a randomized trial show that navigation in bilingual programs reduced time to diagnosis.²¹ Within our cohort, despite the availability of a Spanish speaking navigator, Spanish speaking women returned for biopsies within 37 versus 18 days for the English speakers. This time delay is likely a consequence of Spanish speakers relying on spouses or other family members to bring them to appointments outside the screening facility. In addition, there may be other factors that influence the Hispanic women's acceptance of a biopsy recommendation. Immigration status, for example, may play a role. To instill confidence in our services, CBCC does not enquire about immigration status on patient questionnaires. However, women who are undocumented are often fearful when contacted for follow-up expressing to navigators concerns about payment or possible involvement of authorities despite reassurance that their privacy is protected. We have not formally collected data due to the sensitive nature of immigration status; however, the potential impact on screening behavior is an important issue that should be studied.

A major weakness in this study is that we did not randomize women to receipt of patient navigation or not. A randomized trial would best establish the efficacy of patient navigation. However, our patient care algorithm globally assigns a navigator to all women who have abnormal imaging. For a similar reason, we do not have data representing follow-up rates and time to diagnostic evaluation before the allocation of patient navigators at CBCC for women with abnormal imaging. We also have analyzed data for a 3-year period (2010–2012) only due to the limitations of a new EMR, which permitted complete data for that time period. Nonetheless, the data presented in this study does show that CBCC is effective in supporting women to return for additional workup. The utilization of patient navigators has resulted in an 80% uptake rate for women with abnormal mammography in an expeditious manner (less than 60 days).

Additional areas of future investigation at centers like CBCC that provide care for the underserved is the time from diagnosis to management. It has been hypothesized that delays in not only time to diagnosis but also initiation of treatment contribute to the poorer breast cancer outcomes in minority communities.^{11,14,22} There still remains a dearth of evidence on the potential of patient navigation to improve outcomes related to the diagnosis of cancer in that capacity.⁵ As we work through our patient navigation program to maintain timely diagnostic resolution, we need to evaluate our data on other components of the breast cancer care continuum. Future analysis of CBCC data will also evaluate any impact the Affordable Care Act (ACA), implemented in 2014, will have on the proportion of uninsured patients. Of the group requiring additional workup in this study, 14% were uninsured. Early reports show that under the ACA, a shift in the coverage landscape resulted in a reduction in the uninsured women across multiple states.²³ Whether the time to diagnostic resolution, including the costly needle biopsy, will change also should be assessed. Last, with no provisions for care of undocumented immigrants in the ACA, it remains to be seen if immigration reform policies currently being debated in the government will provide resources to this increasing population.

The work described above complies with the current laws of the country in which they were performed.

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