Patient Navigation Significantly Reduces Delays in Breast Cancer Diagnosis in the District of Columbia

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Abstract

Background: Patient Navigation (PN) originated in Harlem as an intervention to help poor women overcome access barriers to timely breast cancer treatment. Despite rapid, nationally widespread adoption of PN, empirical evidence on its effectiveness is lacking. In 2005, National Cancer Institute initiated a multicenter PN Research Program (PNRP) to measure PN effectiveness for several cancers. The George Washington Cancer Institute, a project participant, established District of Columbia (DC)-PNRP to determine PN's ability to reduce breast cancer diagnostic time (number of days from abnormal screening to definitive diagnosis).

Methods: A total of 2,601 women (1,047 navigated; 1,554 concurrent records-based nonnavigated) were examined for breast cancer from 2006 to 2010 at 9 hospitals/clinics in DC. Analyses included only women who reached complete diagnostic resolution. Differences in diagnostic time between navigation groups were tested with ANOVA models including categorical demographic and treatment variables. Log transformations normalized diagnostic time. Geometric means were estimated and compared using Tukey–Kramer *P* value adjustments.

Results: Average—geometric mean [95% confidence interval (CI)]—diagnostic time (days) was significantly shorter for navigated, 25.1 (21.7, 29.0), than nonnavigated women, 42.1 (35.8, 49.6). Subanalyses revealed significantly shorter average diagnostic time for biopsied navigated women, 26.6 (21.8, 32.5) than biopsied nonnavigated women, 57.5 (46.3, 71.5). Among nonbiopsied women, diagnostic time was shorter for navigated, 27.2 (22.8, 32.4), than nonnavigated women, 34.9 (29.2, 41.7), but not statistically significant.

Conclusions: Navigated women, especially those requiring biopsy, reached their diagnostic resolution significantly faster than nonnavigated women.

Impact: Results support previous findings of PN's positive influence on health care. PN should be a reimbursable expense to assure continuation of PN programs. *Cancer Epidemiol Biomarkers Prev; 21(10); 1655–63.* *©2012 AACR.*

Introduction

Following release of the first Patient Navigation (PN) program report (1), patient navigation efforts have been initiated in many health care facilities throughout the United States. Precise estimates of the actual impact of these programs have not been available; therefore, in 2005, the Center to Reduce Cancer Health Disparities of the National Cancer Institute initiated a multicenter study to compare the effectiveness of navigation in reducing the time to diagnosis and time to treatment of breast, prostate, colon, and cervical cancer. The George Washington Cancer Institute (GWCI) focused on breast cancer in the District of Columbia (DC), as DC has one of the higher breast cancer mortality rates in the country [22.9/100,000 for non-Hispanic whites (NHW); 31.8/100,000 for non-Hispanic blacks (NHB)], a particularly challenging problem because of the large disparity between whites and blacks (2). Nationally, mortality rates ranged from 21.5 to 28.0 for whites and 19.9 to 38.0 for blacks (2).

Although increased screenings and advances in treatment have had a significant impact on reducing mortality rates of black women living in DC from 49.8 (per 100,000) in 1995 to 31.8 (per 100,000) in 2007, disparities between population groups persisted (2). In 2007, mortality rates from breast cancer among white women remained markedly lower than those of their black counterparts

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despite the fact that incidence was higher in whites than blacks (140.4/100,000 vs. 122.4/100,000, respectively) and the proportion of women over age 40 years who had a mammogram in the past year was very similar (66% vs. 63%, respectively; 2).

In 2001, a publicly funded safety-net insurance program for low-income DC residents was implemented and has helped to lower the number of uninsured (10.6% compared with 15.5% nationally); however, among the uninsured individuals, the burden falls disproportionately on blacks (18%) and Hispanics (31%; 3, 4). Furthermore, in a baseline study of women in DC with abnormal breast findings, we found that having health insurance did not reduce the diagnostic delay in NHB; insured minorities waited >2 times longer to reach diagnostic resolution than their NHW counterparts (5).

This study investigates the effect of navigation by comparing the delay between initial identification of a breast abnormality and diagnostic resolution in a multicenter program with navigated patients and proportionally matched (age, race/ethnicity) records-based nonnavigated patients who did not have access to patient navigation. We hypothesized that navigated patients would have shorter diagnostic times than patients without navigation. We examined whether navigation would have the same impact on different subgroups of patients according to race/ethnicity, age, and insurance status.

Materials and Methods

Study design

We prospectively evaluated 2,601 women (1,047 navigated; 1,554 nonnavigated) identified with a suspicious breast abnormality between 2006 and 2010 at 9 hospitals/clinics in DC. Navigated women were examined at 7 hospitals/clinics in DC, including Howard University Hospital, Providence Hospital, Washington Hospital Center's (WHC) Center for Breast Health, WHC Preventorium, Capital Breast Care Center (CBCC), Nueva Vida, and Unity Health Care, Inc. At any of these recruitment intake sites (RIS), women identified with a suspicious breast finding were encouraged to enroll in the study provided they did not fit into one of the exclusion categories established by the PN Research Program (PNRP): age under 18 years, institutionalized, cognitively impaired, currently pregnant, previously navigated for cancer, or prior cancer diagnosis within the past 5 years. Patients who agreed to enroll in the study were asked to sign a consent form. Several RIS received permission from their respective institutional review boards (IRB) to use verbal consent over the telephone. All navigated patients in this study signed informed consent documents approved by one or more IRBs.

Nonnavigated women were selected randomly and retrospectively at the George Washington University (GW) Hospital, Howard University Hospital, Providence Hospital, WHC's Center for Breast Health, Unity Health Care, Inc., and the GW Mammovan (an outreach program focusing on underserved women in DC). The Mammovan served as a source of nonnavigated women for the WHC Preventorium, CBCC, and Nueva Vida—sites that had patient navigation since their inception. A waiver was received from the GW IRB to eliminate the consent process for nonnavigated women because they were all records-based using deidentified data.

Some sites supplied both navigated and nonnavigated subjects, but CBCC, Nueva Vida, and WHC Preventorium had been established as navigation centers from their inception and insisted on navigating all women identified with a suspicious finding. Because CBCC has a predominantly African American population and the other 2 sites focused on Latinas, we were able to choose fairly accurate race and ethnicity-matched control sites, particularly sites visited by the mobile mammography program, for these specific populations.

All nonnavigated women had a suspicious breast abnormality, but did not receive the study intervention, patient navigation, because of the nonavailability of navigation at the time. Nonnavigated women concurrently matched as closely as possible the demographics of navigated women and the presence or absence of confirmed malignancy. Nonnavigated patients were selected using frequency matching on the characteristics of race/ethnicity, time of first detection of abnormality, and diagnosis. Nonnavigated women were identified over the same 5-year period (2006–2010) as navigated patients. Every effort was made to include only patients who never received patient navigation in the nonnavigated group; however, some nonnavigated women may have had access to navigation but it was never documented in their medical records.

The majority of suspicious findings were detected in 2007 (22%), 2008 (38%), and 2009 (32%), with fewer women examined in 2006 (5%) and 2010 (3%).

Our specific study design, "network navigation," including identification of relevant patients, enrollment procedures, and training methods were described in detail in a prior publication (6). During the study, 26 navigators were used and 6 of these women had previously worked as navigators for several years. An additional 9 women had worked closely with patients as nurses, case managers, or community health workers. Our navigators received training in navigation and data collection through DC-PNRP. All navigators in the nationwide PNRPs, including our navigators, also received training at several American Cancer Society-sponsored conferences. GWCI provided additional navigator training through its Center for the Advancement of Cancer Survivorship, Navigation, and Policy.

Definition of outcome and covariates

The goal of this study was to identify the effect of patient navigation on diagnostic time (defined as the number of days from suspicious finding to diagnostic resolution) among those women who had a diagnostic resolution. This study included only women who reached diagnostic resolution and had a known diagnostic time between

0 and 365 days. The data for nonnavigated women were obtained by retrospective record abstraction; therefore, dates of suspicious finding or diagnostic resolution were sometimes missing. These incomplete medical records for some nonnavigated women made it impossible to know whether they achieved diagnostic resolution. Therefore, to make our comparison groups equivalent, we included only navigated and nonnavigated women who had reached diagnostic resolution in all analyses. Including only nonnavigated women who achieved diagnostic resolutions eliminated the potential for any bias from using nonnavigated women with incomplete information. The diagnostic resolutions were primarily either (i) no evidence of malignancy on diagnostic mammogram or (ii) definitive diagnosis by biopsy (benign or malignant).

Suspicious finding was defined as any breast abnormality identified by a clinician during the physical examination, mammography, or ultrasound/MRI. Diagnostic resolution represents the definitive diagnosis for that patient, i.e., the result obtained after diagnostic studies were completed to resolve a suspicious finding. The primary dependent variable of interest was diagnostic time, reported as a continuous variable in days. The primary independent variable of interest was navigation group (navigated, nonnavigated). Covariates included race/ethnicity (NHW, NHB, Hispanic), type of insurance coverage (private, government, none), age (<40, 40–49, 50–59, ≥60), and biopsy as the definitive test (yes, no). Government insurance included federal (Medicaid and Medicare), state, and local government health insurance programs, including the DC government safety-net insurance "Alliance." If a woman had both private and government insurance, she was assigned to the private insurance group. Additional race/ethnicity groups were considered in preliminary analyses as an "other" category but removed from the final analysis as they were too diverse and too small when examining interactions to provide reliable estimates, e.g., Asian ($n = 48$), Native Hawaiian/Pacific Islander ($n = 5$), American Indian/Alaska Native ($n = 7$), and multiracial ($n = 17$).

Data abstraction for nonnavigated patients

All nonnavigated patient data were abstracted from medical records and deidentified before being entered into a central database. All abstracted records were reviewed by a physician with more than 40 years of experience in oncology and pathology. If there were any potential inconsistencies or irregularities, the physician reviewed the original medical record. The exclusion criteria were identical to the criteria used for the navigated patients. Data on marital status, employment, education, income, and primary language—generally obtained via interviews with navigated patients—were not usually provided in the medical records. Consequently, these data were missing for nonnavigated women.

For 427 women seen at the GW Mammovan, race and ethnicity were imputed based on the known demographics of the screening sites, which were predominantly African American, Hispanic, and Asian churches known to be homogeneous with regard to race and ethnicity. Therefore, the imputed values were selected with a high degree of confidence based on the specific site location of the GW Mammovan on the date of initial abnormal screening. Imputation was applied only for those women seen at the GW Mammovan.

Statistical methods

ANOVA models were used to examine the relationships both individually (2-way) and collectively (multiway) between diagnostic time and the aforementioned categorical independent variables: navigation group, race/ethnicity, type of health insurance, age, and biopsy as the definitive test. Study site was included as a fixed effect in all models to control for the different purposively selected sites from where the subjects were obtained; and so, 2-way as opposed to 1-way ANOVA was used for the individual analyses. Two-way interactions between navigation group and each of the categorical variables (i.e., race/ethnicity, type of health insurance, age, and biopsy) were considered in the multivariable analysis. Only those interactions significant at the 0.05 level were included in the final multivariable models. Log transformations were taken on the dependent variable, diagnostic time, to satisfy the model assumption of normality. The average diagnostic time for women having a same day diagnosis was estimated to be approximately 2.5 hours. Therefore, diagnostic times of 0 were replaced with 0.1 in transforming the data. Residual plots showed the log-transformed data satisfied assumptions of normality and homogeneous variance. The Tukey–Kramer method was used for P value adjustment in conducting multiple comparisons.

The Centers for Disease Control and Prevention (CDC) recommended—as part of their National Breast and Cervical Cancer Early Detection Program—that abnormal screens should reach diagnostic confirmation within 60 days (7). The odds of having a diagnostic delay >60 days for the navigation groups were examined by categorizing diagnostic time into 2 groups (≤60 and >60 days) and fitting multiple logistic regression models that included study site as a fixed effect. For comparison, additional models were fit to the data using a cutoff of 30 days—one-half of the number of days recommended by CDC (7).

All statistical tests were 2-sided and the level of significance was set at 0.05. All statistical analyses were conducted using SAS software, Version 9.2 (SAS Institute).

Results

The sample in this study consisted of 2,601 women (1,047 navigated; 1,554 nonnavigated) ranging in age from 18 to 98 years (navigated patient median = 49; nonnavigated patient median = 51). Excluded from all analyses were 36 women (18 navigated, 18 nonnavigated) missing an abnormal screening date, 149 women (112 navigated, 37 nonnavigated) missing a definitive diagnosis date, and 78 women (53 navigated, 25 nonnavigated) with diagnostic times exceeding 365 days (most likely women who

traveled out of our network for diagnosis). PNRP made the decision to censor anyone with a diagnostic time exceeding 365 days at 1 year. We conducted a sensitivity analysis including and excluding these women and did not see dramatic differences in the results.

Descriptive statistics for the remaining 2,338 women with valid diagnostic times are provided in Table 1. Among navigated women, 29% ($n = 17$) of NHW and 12% ($n = 54$) of NHB were known to be uninsured, whereas 78% ($n = 206$) of Hispanics were known to be uninsured. Similarly, among nonnavigated women, 67% ($n = 259$) of Hispanics were known to be uninsured, although only 6% ($n = 8$) of NHWs and 8% ($n = 52$) of NHBs were known to be uninsured.

Summary statistics for diagnostic time are provided in Supplementary Table S1. Histograms and QQ plots revealed that diagnostic time was positively skewed. Log transformations were taken to normalize the data, and the transformed variable was used in our ANOVA models.

Navigated women had a significantly shorter average diagnostic time, 30.1 days (27.2, 33.3), than nonnavigated women, 38.8 days (35.9, 41.9; $P < 0.0001$). A more dramatic difference in average diagnostic times was estimated between navigated and nonnavigated women when controlling for study site [29.8 days (26.3, 33.7) vs. 51.0 days (44.8, 58.1), respectively; $P < 0.0001$]. Results for all 2-way ANOVA models are summarized in Table 2, along with results for the multiway ANOVA model. Navigated women had a significantly shorter adjusted average diagnostic time, 25.1 days (21.7, 29.0), than nonnavigated women, 42.1 days (35.8, 49.6), after controlling for race/ethnicity, type of insurance, age, and study site ($P < 0.0001$).

In addition to this major finding, a subset analysis was conducted on 1,760 women (662 navigated; 1,098 nonnavigated) for whom type of definitive test was recorded to examine the effect of having a biopsy as the definitive test on diagnostic time. In the 2-way ANOVA model (with study site), average diagnostic time was significantly shorter for women who did not have a biopsy, 36.8 days (33.0, 41.0), than women who did have a biopsy as the definitive test, 44.3 days (38.9, 50.5; $P = 0.015$). Adding this variable to our multiway ANOVA model revealed a significant interaction between group and biopsy as the definitive test ($P = 0.0011$). Applying the Tukey–Kramer method for P value adjustment in conducting multiple comparisons, adjusted average diagnostic times were significantly shorter for biopsied navigated women, 26.6 days (21.8, 32.5) than for biopsied nonnavigated women, 57.5 days (46.3, 71.5; $P < 0.0001$). Among nonbiopsied women, diagnostic time was shorter for navigated, 27.2 days (22.8, 32.4), than nonnavigated, 34.9 days (29.2, 41.7), but the difference was not statistically significant ($P = 0.15$). Results are summarized in Fig. 1.

Among identified cancer patients, 93% ($n = 416$) had a biopsy and 7% ($n = 30$) had fine-needle aspiration, although 19% ($n = 244$) of noncancer patients had a

Table 1. Patient characteristics

Variable	Navigated *N* = 864 (37.0%) *N* (%)	Nonnavigated *N* = 1,474 (63.0%) *N* (%)	Total *N* = 2,338 (100%) *N* (%)
Race/ethnicity			
NHW	58 (6.7)	130 (8.8)	188 (8.0)
NHB	466 (53.9)	663 (45.0)	1,129 (48.3)
Hispanic	265 (30.7)	386 (26.2)	651 (27.8)
Other	12 (1.4)	65 (4.4)	77 (3.3)
Unknown	63 (7.3)	230 (15.6)	293 (12.5)
Type of insurance			
Private	328 (38.0)	624 (42.3)	952 (40.7)
Government	170 (19.7)	340 (23.1)	510 (21.8)
None	318 (36.8)	407 (27.6)	725 (31.0)
Unknown	48 (5.6)	103 (7.0)	151 (6.5)
Age group			
<40	177 (20.5)	133 (9.0)	310 (13.3)
40–49	280 (32.4)	566 (38.4)	846 (36.2)
50–59	210 (24.3)	407 (27.6)	617 (26.4)
≥60	189 (21.9)	361 (24.5)	550 (23.5)
Unknown	8 (0.9)	7 (0.5)	15 (0.6)
Biopsy			
Yes	283 (32.8)	546 (37.0)	829 (35.5)
No	488 (56.5)	926 (62.8)	1,414 (60.5)
Unknown	93 (10.8)	2 (0.1)	95 (4.1)

Table 2. Two-way and multiway ANOVA of the time from abnormal screening result to diagnostic resolution among patients receiving and not receiving patient navigation

	Two-way ANOVA[a] ($N = 2,338$)		Multiway ANOVA[b] ($N = 1,842$)	
Variable	***N***	**Geometric mean (95% CI)**	***N***	**Geometric mean (95% CI)**
Navigation group	2,338	—	1,842	—
Navigated	864	29.8 (26.3, 33.7)	743	25.1 (21.7, 29.0)
Nonnavigated	1,474	51.0 (44.8, 58.1)	1,099	42.1 (35.8, 49.6)
Race/ethnicity	1,968	—	1,842	—
NHW	188	19.4 (15.3, 24.6)	184	20.3 (15.9, 25.9)
NHB	1,129	40.2 (35.3, 45.7)	1,042	38.8 (33.8, 44.5)
Hispanic	651	44.2 (37.4, 52.2)	616	43.7 (36.3, 52.6)
Type of insurance	2,187	—	1,842	—
Private	952	33.9 (29.5, 38.9)	780	30.9 (26.2, 36.4)
Government	510	40.1 (34.3, 46.9)	466	34.7 (29.0, 41.5)
None	725	40.1 (34.6, 46.4)	596	32.1 (26.8, 38.4)
Age group	2,323	—	1,842	—
<40	310	26.3 (22.0, 31.4)	220	25.0 (20.1, 31.1)
40–49	846	43.8 (38.8, 49.5)	655	37.4 (32.2, 43.3)
50–59	617	39.8 (34.8, 45.6)	494	37.2 (31.7, 43.8)
≥60	550	38.1 (33.0, 44.1)	473	32.1 (27.1, 38.0)

[a]Each 2-way ANOVA model includes one variable listed and study site as fixed effects.
[b]The multiway ANOVA model includes all variables listed and study site as fixed effects.

biopsy. Navigated women with cancer had a significantly shorter average diagnostic time, 9.8 days (7.5, 12.8), than nonnavigated women with cancer, 39.9 days (28.0, 57.0; $P < 0.0001$). Navigated women without cancer had a nonsignificantly shorter average diagnostic time, 32.5 days (27.5, 38.4), than nonnavigated women without cancer, 37.4 days (30.9, 45.2; $P = 0.61$). Although there was no significant difference in the average diagnostic time between nonnavigated women with and without cancer ($P = 0.99$), navigated women identified with cancer had a significantly shorter average diagnostic time than navigated women without cancer ($P < 0.0001$).

Among patients whose diagnosis was resolved within 1 year, 42% and 63% of navigated women were, respectively, diagnosed within 30 and 60 days, and 30% and 63% of nonnavigated women were, respectively, diagnosed within 30 and 60 days. The odds of having a diagnostic delay >60 days were examined in a multiple logistic

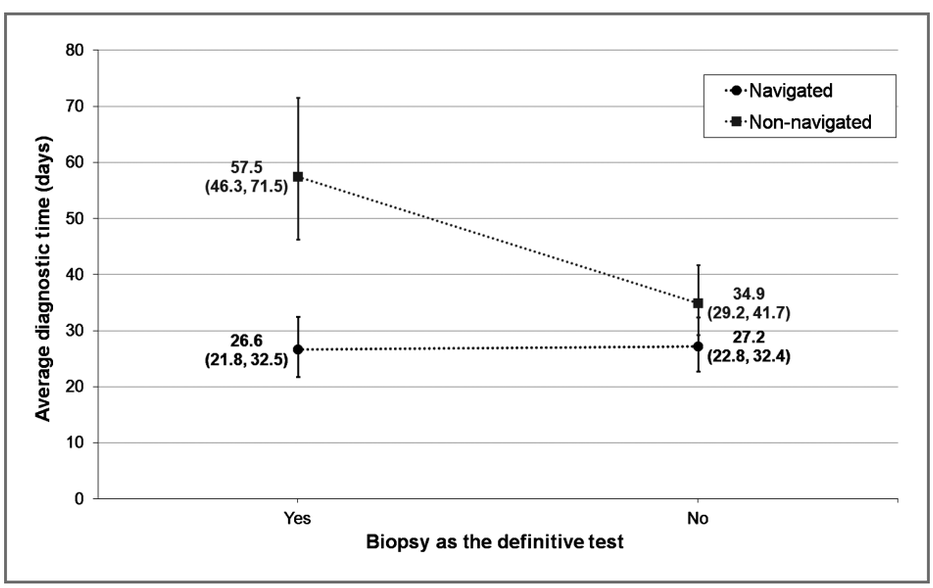

Figure 1. Interaction plot of the average—geometric means (95% CI)—diagnostic times (in days) estimated from multiway ANOVA.

regression model with the independent variables: navigation group, race/ethnicity, type of insurance, age, and study site (Table 3). Among patients whose diagnosis was resolved within 1 year, the odds of having a diagnostic time >60 days for navigated women were not significantly different from nonnavigated women in simple [OR = 0.98, 95% confidence interval (CI): 0.76, 1.27] or multiple (OR = 0.96, 95% CI: 0.72, 1.30) logistic regression models.

Using a 30-day cutoff, the multiple logistic regression model with the aforementioned covariates also included a significant interaction between navigation group and type of insurance ($P = 0.0056$). The odds of having a diagnostic time >30 days for uninsured nonnavigated women were >5 times the odds for uninsured navigated women ($P < 0.0001$). The odds of having a diagnostic time >30 days for privately insured nonnavigated women were 1.7 times the odds for privately insured navigated women ($P = 0.0042$). The odds of having a diagnostic time >30 days for government insured nonnavigated women were 1.3 times the odds for government insured navigated women, but not significant ($P = 0.32$).

Discussion

This study showed navigation was successful in reducing the time from abnormal screening to diagnostic resolution among NHW, NHB, and Hispanic women of all ages, especially for women who had a biopsy as the definitive test. A nearly 4-fold reduction in time to diagnostic resolution was seen when comparing navigated to nonnavigated women who resolved with cancer.

Navigation significantly reduced the odds of having diagnostic delays for both uninsured and privately insured women, with a similar nonsignificant trend seen for women with government insurance. Navigation was most effective in reducing diagnostic times within the first 60 days following abnormal screening.

If we assume that women excluded from the analysis because of missing definitive diagnosis dates never received a definitive diagnosis or took a longer time to obtain a definitive diagnosis, then the disproportionate number of missing diagnosis dates—112 navigated versus 37 nonnavigated—may have biased the results toward seeing a positive effect of navigation. Most likely,

Table 3. Simple and multiple logistic regression of the time from abnormal screening result to diagnostic resolution among patients receiving and not receiving patient navigation

	30-Day cutoff		60-Day cutoff	
	Simple[a] ($n = 2,338$)	Multiple[b] ($n = 1,842$)	Simple[a] ($n = 2,338$)	Multiple[b] ($n = 1,842$)
Variable	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Navigation group	—	—	—	—
Navigated	REF	—	REF	REF
Nonnavigated	1.78 (1.39, 2.29)	—	0.98 (0.76, 1.27)	0.96 (0.72, 1.30)
Race/ethnicity	—	—	—	—
NHW	REF	REF	REF	REF
NHB	2.52 (1.76, 3.60)	2.30 (1.59, 3.32)	1.59 (1.06, 2.40)	1.47 (0.97, 2.24)
Hispanic	4.39 (2.73, 7.06)	3.41 (2.04, 5.69)	1.88 (1.19, 2.98)	1.73 (1.06, 2.83)
Type of insurance	—	—	—	—
Private	REF	—	REF	REF
Government	1.48 (1.16, 1.88)	—	1.25 (0.98, 1.60)	1.17 (0.89, 1.52)
None	1.73 (1.23, 2.43)	—	1.65 (1.25, 2.18)	1.34 (0.95, 1.89)
Age group	—	—	—	—
<40	REF	REF	REF	REF
40–49	1.96 (1.44, 2.66)	1.56 (1.08, 2.26)	1.61 (1.19, 2.16)	1.45 (1.01, 2.06)
50–59	1.56 (1.13, 2.14)	1.42 (0.97, 2.08)	1.46 (1.07, 2.00)	1.43 (0.99, 2.07)
≥60	1.59 (1.15, 2.20)	1.37 (0.93, 2.01)	1.16 (0.83, 1.61)	1.09 (0.74, 1.60)
Group*insurance	—	—	—	—
Private				
Nonnavigated vs. navigated	NA	1.65 (1.17, 2.33)	NA	NA
Government				
Nonnavigated vs. navigated	NA	1.25 (0.81, 1.94)	NA	NA
None				
Nonnavigated vs. navigated	NA	5.41 (2.32, 12.61)	NA	NA

[a]Each simple logistic regression model includes one variable listed and study site as fixed effects.
[b]The multiple logistic regression model includes all variables listed and study site as fixed effects.

however, the majority of these women received a definitive diagnosis outside of the DC-PNRP network so the dates were just not captured in the study data set. This can be inferred from internal business-based, health care systems-related analyses of distribution of cancer care in the DC area.

For both navigated and nonnavigated women, diagnostic time differed significantly based on the type of examination used to determine eligibility for the study. Specifically, women with an abnormal screening mammogram waited >2 times longer to reach diagnostic resolution as women with an abnormal clinical breast examination or an abnormal ultrasound/MRI (data not shown).

We recently published an analysis examining only nonnavigated women from DC-PNRP ($n = 1538$; 5). We found insured minorities waited >2 times longer to reach diagnostic resolution than insured NHWs (5). Having private health insurance did increase the speed of diagnosis in NHBs but privately insured Hispanics had the longest time to diagnosis of any of our race/ethnicity groups: 51 days. Although private insurance helped reduce diagnostic times, number of days until diagnosis remained significantly longer for minorities than for privately insured NHWs suggesting diagnostic delays in minorities are more likely caused by other barriers associated with race/ethnicity than by insurance status. This makes the results obtained when comparing our navigated and nonnavigated patients much more compelling in terms of the benefits of navigation.

A number of studies found results similar to ours in terms of the effectiveness of patient navigation versus usual care using different outcome variables. One study used a design similar to ours in terms of their focus on urban minority women, but examined delay in follow-up after an abnormal mammogram by randomly assigning patients with similar demographics to usual care ($n = 50$) or usual care plus patient navigation ($n = 55$; 8). Navigated women had shorter times to diagnostic resolution than nonnavigated women (25.0 days vs. 42.7 days, $P = 0.001$). At 60 days, 22% of nonnavigated women still did not have a diagnosis versus 6% in the navigated group. Navigated women also had significantly lower anxiety scores and higher satisfaction scores than nonnavigated women. The authors concluded that navigation is effective in improving time to diagnostic resolution, decreasing anxiety, and increasing patient satisfaction (8). Another study found that navigation reduced time between diagnostic biopsy to first consultation with a specialist from 14.6 days to 12.8 days and time between diagnostic biopsy to first treatment from 30 days to 26.2 days (9). The majority of patient barriers (71%) were resolved by the time treatment was initiated (9).

Although we did not assess patient satisfaction or perspectives in our study, a number of other studies examined patients' feelings and opinions as outcome variables and they also found positive results for patient navigation. In comparing 72 navigated patients and 181 nonnavigated patients referred to a hospital because of an abnormal mammogram, navigated patients were significantly more likely to definitely understand what to expect at their visit (79% vs. 60%), to receive a reminder letter or phone call, and to feel welcome (10). Assessing patient perspectives of patient navigation is needed to evaluate navigation programs. An analysis of navigation effectiveness for low-income African Americans noted that barriers to diagnostic follow-up or treatment were identified by the navigators and this helped the navigators to guide patients through the health care system as evidenced by the fact that 93% of patients kept their appointments (11). Among 176 Korean women randomly assigned to usual care or patient navigation, self-reported completion of follow-up procedures was 97% for navigated and 67% for non-navigated ($P < 0.001$) providing more evidence for the effectiveness of navigation in another minority group, Asians (12). These studies provide support for patient navigation in general, along with our study results.

Several other studies found patient navigation to be a significantly effective intervention in patient care using different study designs and outcome variables (13–21); however, 2 studies did not find that patient navigation was any better than usual care (22, 23). A review of the results to-date on navigation effectiveness found that most studies had significant limitations including no control group, small sample size, and contamination with other interventions (24).

The DC site is unique compared with all other national PNRP sites in its "network navigation" approach. Navigators from a citywide partnership of unaffiliated clinical and community sites were trained to work collaboratively with open communication across sites, within a citywide network to enroll patients in the study and assure each patient received timely, quality care (6). Three techniques helped enhance care coordination and assure appropriate referral strategies between sites: (i) conducting frequent staff trainings, (ii) promoting increased communication between navigators, and (iii) sharing information about community resources.

We instituted a longitudinal navigation program that follows the patient from outreach through survivorship (6). In a review article discussing navigation generally, our program was perfectly defined: "patient navigation is a system, as opposed to a person, comprised primarily of navigators and directors that work together to remove barriers and facilitate access in a well-defined course of care" (25).

A strength of our study is the sizeable sample in both the navigated and nonnavigated groups representative of all demographics in the DC metropolitan area. Larger sample sizes help to increase statistical power and add to the validity of the findings. In addition, our subjects were identified at a variety of facilities including major medical centers, a storefront mammography unit, a clinic geared specifically to Hispanics, a nonclinical community site focused on assisting Hispanic women with cancer and obtaining cancer screening, and clinics specifically

available to the poor. This helped to assure a representative sample of the underserved—the population of greatest concern in terms of cancer morbidity and mortality.

A limitation of this study is that it was based on a sample selected from a single metropolitan area that was not probabilistic, i.e., random selection was not used. In addition, all our patients had reached diagnostic resolution; hence, there was no opportunity to assess differences in diagnostic resolution rates between navigated and nonnavigated women. Also, race and ethnicity had to be imputed for 427 nonnavigated women seen by the GW Mammovan. As stated previously, the imputed values were selected with a high degree of confidence based on specific locations of the GW Mammovan on the date of initial abnormal screening, which were primarily African American, Hispanic, and Asian churches.

In addition, insurance status may have changed for some patients during the interval being assessed. Also, medical records were relied on to assess variables and outcomes for nonnavigated patients rather than self-reports, although some studies found medical records provided similar results as self-reports, administrative records, and health department records (26–29). Because we used only one chart reviewer for all nonnavigated patients, interrater reliability, an important assessment of the quality of data abstraction, could not be calculated.

Despite these limitations, this study clearly shows navigation is effective in decreasing time to diagnostic resolution particularly among women who have a biopsy and have a diagnostic resolution of cancer. Patient navigation should be implemented as a means to reduce diagnostic times. We are currently working on an analysis of the barriers faced by subjects in our study. A few other researchers have examined this issue (30–32) with varying results. Analyses of the national PNRP data are currently being conducted, including further analysis of navigation's cost-effectiveness. These results will determine whether patient navigation will be viewed positively by national health policy makers and will become a usual part of the cancer care process with insurance reimbursement for patient navigation.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Authors' Contributions

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