Follow-Up and Timeliness After an Abnormal Cancer Screening Among Underserved, Urban Women in a Patient Navigation Program

Talar W. Markossian[1], Julie S. Darnell[2], and Elizabeth A. Calhoun[2]

Abstract

Background: We evaluated the efficacy of a Chicago-based cancer patient navigation program developed to increase the proportion of patients reaching diagnostic resolution and reduce the time from abnormal screening test to definitive diagnostic resolution.

Methods: Women with an abnormal breast ($n = 352$) or cervical ($n = 545$) cancer screening test were recruited for the quasi-experimental study. Navigation subjects originated from five federally qualified health center sites and one safety net hospital. Records-based concurrent control subjects were selected from 20 sites. Control sites had similar characteristics to the navigated sites in terms of patient volume, racial/ethnic composition, and payor mix. Mixed-effects logistic regression and Cox proportional hazard regression analyses were conducted to compare navigation and control patients reaching diagnostic resolution by 60 days and time to resolution, adjusting for demographic covariates and site.

Results: Compared with controls, the breast navigation group had shorter time to diagnostic resolution (aHR = 1.65, CI = 1.20–2.28) and the cervical navigation group had shorter time to diagnostic resolution for those who resolved after 30 days (aHR = 2.31, CI = 1.75–3.06), with no difference before 30 days (aHR = 1.42, CI = 0.83–2.43). Variables significantly associated with longer time to resolution for breast cancer screening abnormalities were being older, never partnered, abnormal mammogram and BI-RADS 3, and being younger and Black for cervical abnormalities.

Conclusions: Patient navigation reduces time from abnormal cancer finding to definitive diagnosis in underserved women.

Impact: Results support efforts to use patient navigation as a strategy to reduce cancer disparities among socioeconomically disadvantaged women. *Cancer Epidemiol Biomarkers Prev; 21(10); 1691–700. ©2012 AACR.*

Introduction

Breast and cervical cancers remain among the most prevalent causes of cancer death among women for which early detection and timely diagnosis and treatment could improve prognosis and prevent mortality (1). Routine screening mammography and Papanicolaou (Pap) test screening with timely and appropriate follow-up has been proven effective in decreasing mortality from breast (2, 3) and cervical cancers (4), respectively. Low-income ethnic or racial minority women experience a variety of personal, for example, race/ethnicity and socioeconomic status (SES), provider, for example, race and age biases, and health system level barriers, for example, organizational and structural factors when seeking health care (5, 6). As a result, these women are less likely to receive recommended and timely cancer care when compared with their more affluent counterparts (5–9). Cancer patient navigation (PN) has been advocated as a strategy to address barriers to obtaining recommended and timely cancer care in underserved populations. The largest and longest effort to test the efficacy of PN is the $25 million, 5-year Patient Navigation Research Program (PNRP) undertaken by the National Cancer Institute (NCI). According to the PNRP definition, cancer navigation is "support and guidance offered to patients with abnormal cancer screening or diagnosis in helping them overcome barriers to timely and quality cancer care" (10).

While a growing number of studies have documented the efficacy of PN in improving adherence rates and timeliness to follow-up diagnostic resolution after the detection of a screening abnormality (11–13), the literature suffers from important limitations. There have been few studies published since a 2008 review of PN programs (11, 12). Most studies have targeted breast cancer, with only a few targeting cervical cancer (11).

Authors' Affiliations: [1]Health Policy and Management, Jiann-Ping Hsu College of Public Health, Georgia Southern University, Statesboro, Georgia; and [2]Division of Health Policy and Administration, School of Public Health, University of Illinois at Chicago, Chicago, Illinois

Corresponding Author: Talar W. Markossian, Jiann-Ping Hsu College of Public Health, Georgia Southern University, 501 Forest Drive, P.O. Box 8015, Statesboro, GA 30460. Phone: 912-478-7901; Fax: 912-478-0171; E-mail: tmarkossian@georgiasouthern.edu

doi: 10.1158/1055-9965.EPI-12-0535

Several of these studies contain methodologic weaknesses, including small sample sizes, a lack of a usual care comparison group, and the combination of PN with other intervention components (12, 13). Also, it is difficult to compare findings across studies because they used varying definitions of "diagnostic resolution" and "timeliness" (11).

The study objective is to evaluate the efficacy of PN among low-income, minority women with an abnormal breast or cervical cancer screening test in Chicago. We hypothesized that compared with controls, a greater proportion of navigated women would reach diagnostic resolution by 60 days. We hypothesized further that the time from abnormal screening test to definitive diagnostic resolution would be shorter for navigated patients. A secondary objective of this study is to identify personal characteristics that are associated with the outcomes of interest.

This study offers several advantages over earlier research as it includes a comparative arm, allows for comparisons between breast and cervical cancers, and includes both Black and Hispanic participants. Also, being one of the ten projects of the national PNRP makes it possible to compare findings with the other PNRP projects (14). Results will inform providers about the efficacy of adopting PN in their practices and will help them identify patients who might benefit the most from navigation.

Materials and Methods

Study design

The Chicago Cancer Navigation Project (CCNP) was conducted from October 2005 through March 2010 and is one of the 10 NCI-supported PNRP projects developed in 9 sites across the country (10). The CCNP used a nonrandomized, controlled design and targeted low-income, minority women seeking medical care in the safety net system. Overall, navigated and control subjects originated from 20 different primary care delivery sites. Of these, 19 were part of a single federally qualified health center (FQHC) network and 1 was a hospital-based ambulatory care center.

Similar numbers of navigated and control patients were recruited from the single, hospital-based ambulatory site using individual nonrandom assignment. Because the hospital is a major tertiary referral center in the region, all control subjects and 80% of navigated subjects entered the study with a cancer diagnosis.

Within the FQHC network, 5 navigation sites were chosen because they served a majority African American or Latina population and had logistic ease of administering the navigation intervention. Patients seeking care within the FQHC network, who became navigated subjects, were patients of a clinic that had an on-site navigator. The 14 medical record-based control sites were selected because they had similar characteristics to the navigated sites according to patient volume, racial/ethnic composition, and payor mix. Control subjects remained controls even if they changed clinics to receive follow-up care at a navigation site.

Study participants

Adult women whose breast or cervical cancer screening test was abnormal were eligible to participate in this study. A breast cancer screening test was defined as "abnormal" if there was (i) confirmed breast mass or other abnormality suspicious for cancer as a result of clinical breast exam (CBE) or (ii) suspicious or incomplete mammogram, ultrasound, or magnetic resonance imaging results [American College of Radiology Breast Imaging and Reporting Data Systems (BI-RADS)]. A cervical abnormality was defined as a (i) visible or suspicious lesion on cervix or (ii) either low- or high-grade abnormal Pap test. The index screening served as the point of identification and enrollment of women into the study. All eligible patients were approached and clinics refusals varied from 3% to 5% ($N = 1{,}048$).

Women were ineligible if they were younger than 18 years, being treated (or had been treated) for another cancer, or pregnant. Because the outcome of interest in this study is diagnostic resolution, patients who entered the study with a breast cancer diagnosis ($n = 81$) or a cervical cancer diagnosis ($n = 66$) were omitted. Those with concurrent breast and cervical screening abnormalities ($n = 4$) also were excluded. A total of 897 women (breast = 352 and cervical = 545) participated in this study. (Fig. 1)

Patient navigation intervention

In line with PNRP's definition of navigation and navigator role (10), CCNP was guided by the principles of case management (15). CCNP had 4 major components including identifying and recruiting patients, identifying individual barriers to receiving care, developing and implementing an individualized plan to address the barriers, and tracking patients through problem resolution. CCNP replaced and extended the regular standard of care protocol at the clinics. The standard of care protocol included up to 2 phone calls from the clinic asking women to return for test results and a third and final attempt via certified letter when an abnormal result was recorded.

The CCNP team consisted of two master's-prepared licensed clinical social workers and 2 lay patient navigators. The social worker navigators were part of a larger American Cancer Society PN program and had access to statewide network of resources. The lay navigators were high school graduates and were racially/ethically concordant with the patients. One of the lay navigators was bilingual in Spanish and English. Navigators participated in annual national training sessions with a standardized curriculum developed by experts from the national PNRP program (16).

Navigators were assigned to specific clinics based on patient population characteristics, patients' needs, and workload. The PN team collectively sought to identify and resolve barriers to receiving timely follow-up cancer

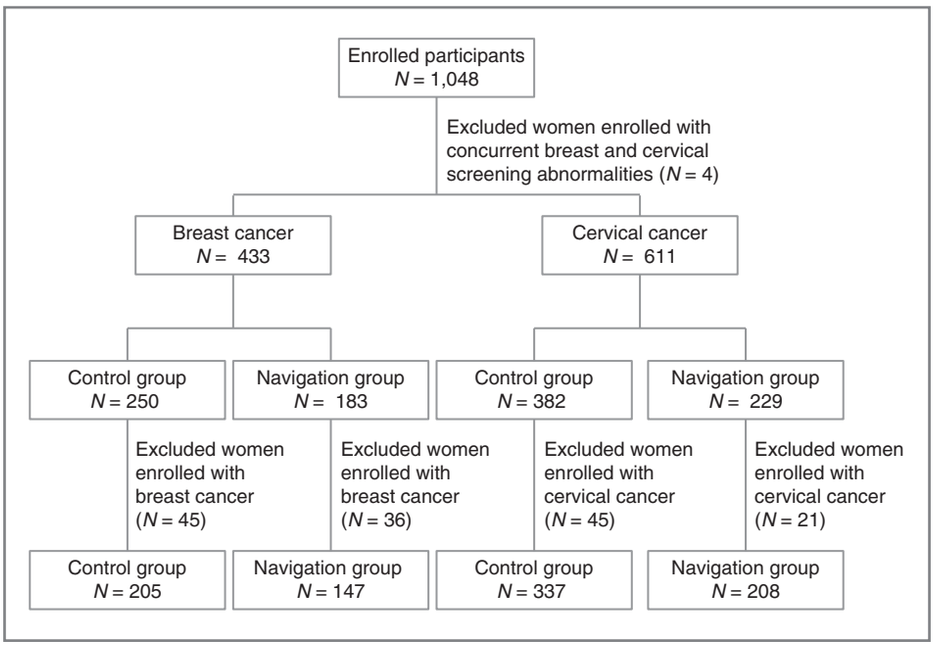

Figure 1. Study sample of nonrandomized, controlled trial of patient navigation among 897 women with an abnormal breast or cervical cancer screening test (2005–2010).

care. The social worker navigators assumed the role of team leaders and provided support for lay navigators in dealing with patients with complex barriers. For each patient, the intensity of resources required for successful navigation was tailored based on identified needs. In addition to resolving barriers to receiving timely follow-up cancer care, navigation services included helping enroll patients in public assistance programs and linking patients to community resources. Women in the control group received the regular standard of care.

Data collection

Navigators recruited eligible women for the navigation intervention by phone and in person generally within one week of the documentation of the abnormal screening test results. Written consent was obtained for all navigated subjects. Consent from control subjects was obtained through the primary care delivery sites' standard consent process. Clinical data were collected from medical charts. The study protocols were approved by Institutional Review Board of The University of Illinois at Chicago (Chicago, IL).

Study variables

The main outcome measures were having reached diagnostic resolution by 60 days and time to diagnostic resolution. Diagnostic resolution was achieved when a patient received all tests necessary to make a final determination of cancer or no cancer. Information on receipt of diagnostic resolution was dichotomized as to whether or not diagnostic resolution was achieved by 60 days (yes/no). The time period of 60 days corresponds to the National Breast and Cervical Cancer Early Detection program (NBCCEDP) guidelines for timely follow-up for women with abnormal screening results (17). Time to diagnostic resolution was calculated as the number of days between the initial abnormal screening test and confirmation of a definitive cancer diagnosis in the medical chart (malignant or benign). Patients who did not reach diagnostic resolution within the predefined study period of 365 days were censored at 365 days. To ensure similar treatment of navigated and controls, when navigator notes indicated that they were unable to reach a patient by phone or mail, time to diagnostic resolution was censored at the end of the study period (365 days).

The PNRP design and analysis committee required all sites to use standard patient covariates in all analyses to allow for comparisons of findings across sites. Covariates included race/ethnicity (black, white, Hispanic, other), age at initial abnormal screening, marital status, insurance status (uninsured, public, private), and language (English, Spanish, other). In our study, language was dropped from the analysis because of multicollinearity with race. In addition, we controlled for relevant clinical information; these include eligibility due to abnormal CBE (yes/no), BI-RADS score (0, 3, 4/5/other) for breast cancer subjects and eligibility due to abnormal Pap smear finding (low- or high-grade) for cervical cancer subjects (18–21). Low-grade signified atypical cells of undetermined significance (ASCUS) with positive high-risk serotype, atypical glandular cells, low-grade squamous intraepithelial lesion (LGSIL), and ASCUS with no reflex human papillomavirus (HPV) conducted. High-grade signified high-grade squamous intraepithelial lesion (HGSIL) or microinvasion.

Statistical analysis

Descriptive statistics were used to provide overall characteristics of the study population. χ^2 tests for categorical variables and t tests for continuous variables were

conducted to assess differences between the study groups. All reported P values are 2-sided, and statistical significance was defined as $\alpha = 0.05$.

A mixed-effects logistic model was used to estimate the odds of receiving diagnostic resolution by 60 days in the navigated group compared with the control group, controlling for demographic and clinical covariates. Separate analyses were carried out for breast and cervical cancer groups. Site was treated as a random effect and given its own intercept in the model. Survival analysis was used to compare time from initial abnormal screening test to date of diagnostic resolution for the navigated and control groups. Kaplan–Meier curves were developed to plot survival time for success in receiving a diagnostic resolution while addressing censoring of unresolved cases. The Cox proportional hazards model with shared frailty was used to obtain hazard ratios (HRs) with 95% confidence interval (CI). Models controlled for demographic and clinical covariates. Gamma-shared frailty was used to model the within-sites correlation. Higher HRs signify a shorter time interval between initial abnormal screening and receipt of a definitive diagnosis in the navigation group relative to the controls.

By testing the interaction of navigation with time in the breast and cervical models, the proportional hazards assumption was assessed and met for breast cancer and violated for cervical cancer, as the coefficient of the interaction of navigation with time was significant in the cervical model. Stratification would have been an option for cervical cancer analysis. However, stratified Cox regression is primarily suitable for nuisance variables because it is not possible to obtain estimation and inference for the effects of the stratifying variable. Therefore, for the cervical cancer analysis, because the survival curves for the navigated and controls crossed at approximately 30 days, we included an interaction term between study type (navigation vs. control) and time allowing differential effects of PN over days 0 to 30 and days 31 to 365.

Logistic regression analyses and survival analyses were repeated with and without Whites and Others, who comprised 2% of subjects. The inclusion or exclusion of Whites and Others did not meaningfully change the results and therefore these subjects were dropped from the analyses. All statistical analyses were conducted using STATA version 11.2 (StataCorp).

Results

Descriptive characteristics of breast cancer participants

In Table 1, the characteristics of the study population are displayed according to navigation or control groups and breast cancer or cervical cancer navigation. A total of 352 women were included in the breast cancer component, of whom 147 received navigation and 205 were controls. The majority of participants were Hispanic (66%) followed by Black (32%); and more than half participants spoke Spanish (57%) with the remaining participants speaking English (38%) or other languages (5%). Navigated and control arms were similar in terms of primary language, marital status, and BI-RADS score for women eligible due to abnormal mammogram. In both arms, higher percentages of women were Spanish speaking (navigated = 59% and control = 56%), never partnered (navigated = 46% and control = 48%), and had BI-RADS score 0 at the time of enrollment (navigated = 93% and control = 81%). Navigated and control arms differed by race/ethnicity, age, insurance status, and eligibility test. Women in the navigation arm were more likely to be Hispanic (71% vs. 62%, $P = 0.050$), younger at the time of the initial screening (41.2 vs. 49.3 years, $P < 0.0001$), uninsured (84% vs. 59%, $P < 0.0001$), and eligible due to abnormal CBE (62% vs. 11%, $P < 0.0001$).

Descriptive characteristics of cervical cancer participants

Exactly 545 women were included in the cervical cancer component, of whom 208 received navigation and 337 were controls. Navigated and control arms were similar in terms of race/ethnicity, age, and marital status. In both arms, higher percentages of women were Black (navigated = 65% and control = 62%), never partnered (navigated = 76% and control = 82%); the 2 arms also had similar mean ages (navigated = 29.6 and control = 30.0 years). Navigated and control arms differed by primary language, insurance status, and eligibility status. Navigated women were more likely to be English speaking (73% vs. 65%, $P = 0.007$), have public insurance (52% vs. 40%, $P = 0.003$), have high-grade Pap (15% vs. 6%, $P = 0.001$).

Percentage and time to resolution for breast cancer screening navigation

Figure 2 shows that, compared with control subjects, a higher percentage of navigated subjects reached diagnostic resolution of breast cancer by 60 days (83.0% vs. 52.7%) and by 365 days (98.7% vs. 81.0%). Kaplan–Meier curves suggest that, compared with controls, women in the navigated group experienced shorter time to resolution and a greater proportion of them reached diagnostic resolution by 365 days (Fig. 3). In Table 2, compared with controls, navigated women had shorter time to diagnostic resolution [adjusted HR (aHR), 1.65; CI, 1.20–2.28; $P = 0.002$). Variables significantly associated with longer time to diagnostic resolution included being older (aHR 0.98, CI 0.97–0.99, $P = 0.009$), never partnered compared with currently partnered (aHR 0.67, CI 0.50–0.91, $P = 0.01$), eligible due to abnormal mammogram/ultrasound compared with eligible due to CBE (aHR 0.55, CI 0.40–0.78, $P = 0.001$) or BI-RADS 3 finding for initial abnormal mammogram/ultrasound compared with all other women (aHR 0.37, CI 0.23–0.61, $P < 0.0001$).

In adjusted analysis, navigation was not significantly associated with the odds of receiving diagnostic resolution of breast cancer within 60 days [adjusted OR (aOR) 1.88, CI 0.75–4.70, $P = 0.175$]. Age and mammogram/ultrasound findings were significantly associated with

Table 1. Characteristics of study participants of the Chicago Cancer Navigation Project

	Breast Cancer ($N = 352$[a])				Cervical Cancer ($N = 545$[a])			
	Controls ($n = 205$)	Navigated ($n = 147$)			Controls ($n = 337$)	Navigated ($n = 208$)		
Characteristics	*N* (%)	*N* (%)	*P* value	All sites	*N* (%)	*N* (%)	*P* value	All sites
Race and ethnicity			0.050[b]				0.915[b]	
Black	68 (34%)	43 (29%)		111 (32%)	209 (62%)	136 (65%)		345 (63%)
Hispanic	126 (62%)	104 (71%)		230 (66%)	120 (36%)	69 (33%)		189 (35%)
White	6 (3%)	_		6 (1%)	5 (1%)	3 (2%)		8 (1%)
Other	2 (1%)	_		2 (1%)	1 (1%)	_		1 (1%)
Primary language			0.131				0.007[b]	
English	84 (41%)	50 (34%)		134 (38%)	220 (65%)	152 (73%)		372 (68%)
Spanish	115 (56%)	87 (59%)		202 (57%)	113 (34%)	49 (24%)		162 (30%)
Other	6 (3%)	10 (7%)		16 (5%)	3 (1%)	7 (3%)		10 (2%)
Age (mean, SD)	49.3 (9.4)	41.2 (10.5)	<0.0001	45.9 (10.7)	30.0 (10.5)	29.6 (10.3)	0.646	29.9 (10.4)
Marital status			0.772				0.182	
Current partnered	73 (37%)	54 (37%)		127 (37%)	44 (13%)	33 (16%)		77 (14%)
Never partnered	96 (48%)	66 (46%)		162 (47%)	270 (82%)	157 (76%)		427 (80%)
Past partnered	29 (15%)	25 (17%)		54 (16%)	15 (5%)	16 (8%)		31 (6%)
Insurance status			<0.0001				0.003	
Private	40 (20%)	6 (4%)		46 (13%)	76 (23%)	25 (12%)		101 (19%)
Uninsured	121 (59%)	122 (84%)		243 (70%)	126 (37%)	74 (36%)		200 (37%)
Public	43 (21%)	18 (12%)		61 (17%)	135 (40%)	107 (52%)		242 (44%)
Eligibility for breast			<0.0001[b]					
Abnormal clinical breast exam	22 (11%)	91 (62%)		113 (32%)				
Abnormal mammogram	183 (89%)	55 (37%)		238 (67%)				
BI-RADS 0	*148 (81%)*	*51 (93%)*	0.065[b]	199 (83%)				
BI-RADS 3	*32 (17%)*	*3 (5%)*		35 (15%)				
BI-RADS 4/5/other	*3 (2%)*	*1 (2%)*		4 (2%)				
Abnormal ultrasound	_	1 (1%)		1 (1%)				
BI-RADS other		*1 (100%)*						
Eligibility for cervical							0.001	
Abnormal Pap low-grade					314 (94%)	177 (85%)		491 (91%)
Abnormal Pap high-grade					20 (6%)	31 (15%)		51 (9%)

[a]Not all variables sum to $N = 352$ for breast cancer and $N = 545$ for cervical cancer because of missing data in some of the variables.
[b]*P* value calculated using Fisher exact test.

receiving diagnostic resolution within 60 days, controlling for all else.

Percentage and time to resolution for cervical cancer screening navigation

A higher percentage of women in the navigated group reached diagnostic resolution by 60 days (52.4% vs. 24.9%) and by 365 days (88.5% vs. 70.3%) compared with women in the control group (Fig. 2). In Fig. 3, there was a superimposition of the Kaplan–Meier curves through about 30 days suggesting no difference in outcomes, after which women in the navigated group showed an improvement in the time to resolution and in the proportion of women who reached diagnostic resolution by 365 days compared with controls. In Table 3, in the first 30 days, PN was not significantly associated with a greater likelihood of diagnostic resolution of cervical cancer (aHR 1.42, CI 0.83–2.43, $P = 0.195$). However, from days 31 through 365, compared with controls, navigated women had shorter time to diagnostic resolution (aHR 2.31, CI 1.75–3.06, $P < 0.0001$). Race and age were significantly associated with time to diagnostic resolution. Compared with Blacks, Hispanic women had shorter time to diagnostic resolution (aHR 1.62, CI 1.23–2.13, p = 0.001). Compared with younger women, older women had shorter time to diagnostic resolution (aHR 1.01, CI 1.00–1.02, $P = 0.025$).

Compared with controls, the odds of diagnostic resolution within 60 days were greater in the navigation group (aOR 3.57, CI 2.38–5.35, $P < 0.0001$), and this difference achieved statistical significance. Race and insurance status were significantly associated with receiving diagnostic resolution within 60 days. Compared with Blacks,

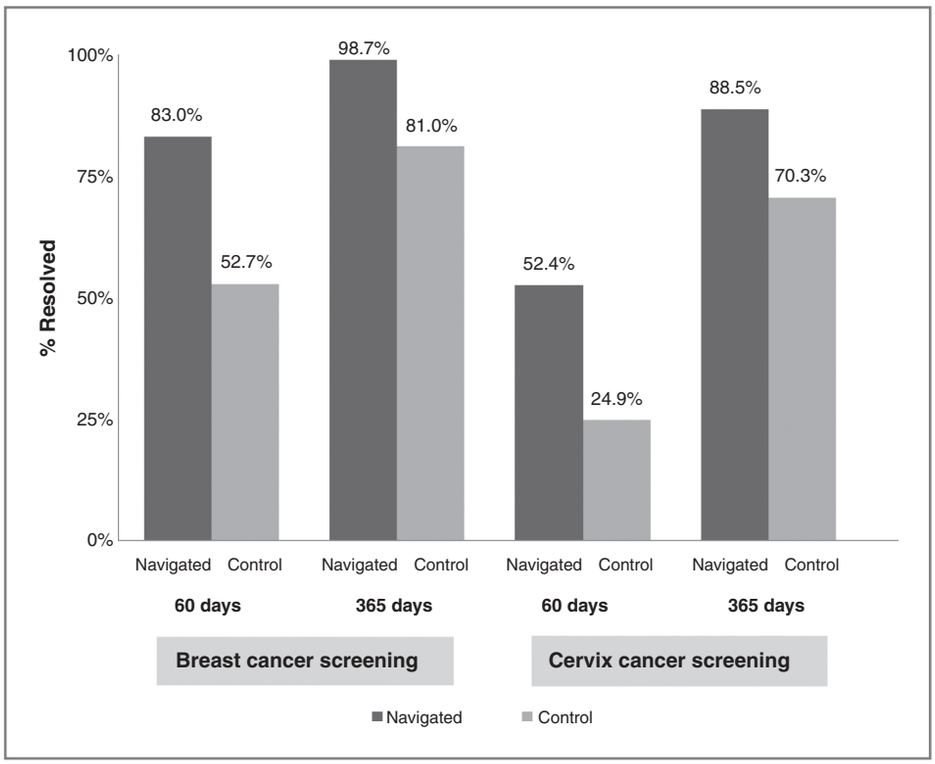

Figure 2. Unadjusted percentage of subjects who reached diagnostic resolution by 60 days and 365 days in the Chicago Cancer Navigation Project, comparing navigated and control cases for breast and cervical cancer screening.

Hispanic women had 93% increased odds of receiving diagnostic resolution within 60 days (aOR 1.93, CI 1.22–3.07, $P = 0.005$). Compared with privately insured, uninsured women had significantly increased odds of receiving diagnostic resolution within 60 days (aOR 2.49, CI 1.36–4.58, $P = 0.003$).

Discussion

Results from our study contribute in several ways to advancing knowledge about the efficacy of PN. Notably, our PN intervention, targeted to urban women living in poor neighborhoods, is shown to yield benefits for highly disadvantaged populations who often face tremendous barriers receiving timely cancer care (22). Throughout the United States, residents of highly urbanized areas (23) and impoverished inner-city communities (22, 24–26) have higher late-stage cancer risk compared with nonurban residents, and our results suggest that these residents could benefit from similarly designed PN programs.

For the entire study period, breast cancer navigation was associated with shorter time to diagnostic resolution (aHR 1.65, CI 1.20–2.28, $P = 0.002$). In comparison, in the first 30 days, cervical cancer navigation was not significantly associated with shorter time to diagnostic resolution (aHR 1.42, CI 0.83–2.43, $P = 0.195$). However, from days 31 through 365, compared with controls, navigated women had shorter time to diagnostic resolution (aHR 2.31, CI 1.75–3.06, $P < 0.0001$). These findings may be due

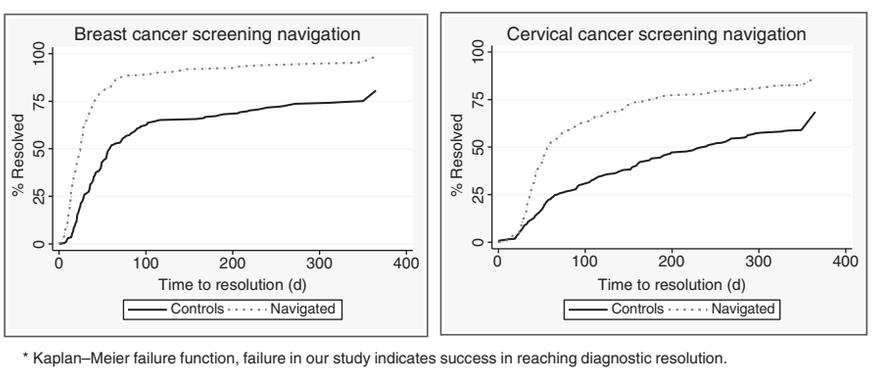

Figure 3. Kaplan–Meier curves* for success in reaching diagnostic resolution in the Chicago Cancer Navigation Program.

* Kaplan–Meier failure function, failure in our study indicates success in reaching diagnostic resolution.

Table 2. Factors associated with time to diagnostic resolution (T1) following breast cancer screening abnormality in the Chicago Cancer Navigation Project

Characteristics	T1 in days aHR[a,b] (95%CI)	60 days aOR[b] (95%CI)
Patient navigation		
Control sites	Ref[c]	Ref
Navigated Sites	1.65** (1.20–2.28)	1.88 (0.75–4.70)
Race/ethnicity[d]		
Black	Ref	Ref
Hispanic	1.43 (0.97–2.10)	1.52 (0.63–3.67)
Age	0.98** (0.97–0.99)	0.96* (0.92–0.99)
Insurance status		
Private	Ref	Ref
Uninsured	1.04 (0.68–1.60)	1.34 (0.56–3.21)
Public	1.16 (0.73–1.84)	0.87 (0.33–2.28)
Marital status		
Current partnered	Ref	Ref
Never partnered	0.67** (0.50–0.91)	0.54 (0.26–1.12)
Past partnered	0.82 (0.57–1.18)	0.85 (0.34–2.13)
Eligibility		
Clinical Breast Exam	Ref	Ref
Mammogram/ ultrasound	0.55** (0.40–0.78)	0.47 (0.18–1.25)
Mammogram/ ultrasound findings		
All other women	Ref	Ref
BI-RADS 3	0.37** (0.23–0.61)	0.08** (0.02–0.26)

[a]Higher HR corresponds to shorter time interval.
[b]Analyses adjusted for all variables listed in the table and site random effects.
[c]Ref, reference group.
[d]Whites and Others only comprised 2% of cases in the sample and dropping them from the analyses did not change the results.
*, $P < 0.05$ and **, $P < 0.01$.

Table 3. Factors associated with time to diagnostic resolution (T1) following cervical cancer screening abnormality in the Chicago Cancer Navigation Project participants

Characteristics	T1 in days aHR[a,b] (95%CI)	60 days aOR[b] (95%CI)
Patient navigation		
Control sites	Ref[c]	Ref
Navigated Sites		3.57** (2.38–5.35)
Resolution before 30 days	1.42 (0.83–2.43)	
Resolution after 30 days	2.31** (1.75–3.06)	
Race/ethnicity[d]		
Black	Ref	Ref
Hispanic	1.62** (1.23–2.13)	1.93** (1.22–3.07)
Age	1.01* (1.00–1.02)	1.02 (0.99–1.04)
Insurance status		
Private	Ref	Ref
Uninsured	1.26 (0.92–1.71)	2.49** (1.36–4.58)
Public	1.21 (0.91–1.62)	1.37 (0.76–2.48)
Marital status		
Current partnered	Ref	Ref
Never partnered	0.90 (0.66–1.22)	0.83 (0.46–1.51)
Past partnered	0.81 (0.51–1.29)	0.75 (0.30–1.88)
Pap smear findings		
Low-grade	Ref	Ref
High-grade	0.99 (0.98–1.02)	1.01 (0.98–1.03)

[a]Higher HR corresponds to shorter time interval.
[b]Analyses adjusted for all variables listed in the table and site random effects.
[c]Ref, reference group.
[d]Whites and Others only comprised 2% of cases in the sample and dropping them from the analyses did not change the results.
*, $P < 0.05$ and **, $P < 0.01$.

to several factors. One possible reason is that cervical cancer navigation operates differently than breast cancer navigation, and the disparate findings may be due to the differences in the nature of the follow-up services or to underlying differences in the characteristics of the population. Another possible reason is that cervical cancer navigation has lagged effects, benefiting those encountering barriers or delays to timely follow-up more than those who encounter fewer problems and/or are motivated to follow-up efficiently within the first 30 days (13% of cases and controls had resolution within this time). Rather, navigation benefits those women with potential barriers or delays to timely follow-up, which take more than 30 days to resolve. Identifying which populations can most benefit from PN and the conditions under which PN would be most effective ought to be the focus of further study.

Our findings are similar to previous research that found higher adherence rates (27) and shorter follow-up time (28) for abnormal breast conditions compared with gynecologic conditions. The reported differences in adherence and timeliness for breast compared with gynecologic abnormalities may reflect several factors. One possible reason is that women have more concerns about breast abnormalities compared with gynecologic abnormalities (27). Another possible reason is the clinical imperative for more rapid resolution for breast abnormalities, with a longer timeline for cervical abnormalities. Or, it may simply be due to the differences in the characteristics of women in our sample navigated for breast and cervical cancers.

In our study, Hispanic women had shorter time to cervical cancer diagnostic resolution compared with Blacks (aHR 1.62, CI 1.23–2.13, $P = 0.001$). The association failed to reach similar statistical significance at $P < 0.05$ in the breast cancer PN intervention (aHR 1.43, CI 0.97–2.10, $P = 0.072$). Earlier research found that screening and follow-up interventions often yielded only modest improvements in Hispanic women, with language being a major barrier to experiencing improvement (29). One possible explanation for our more favorable findings for Hispanic participants is that the lay navigator was bilingual and ethnically concordant with the navigated patients. Another possible explanation might be that Blacks and Latinos have different barriers to follow-up care for breast and cervical abnormalities. A separate analysis of the CCNP data examining patient barriers showed that compared with Blacks, Latinos had more insurance-related barriers that were easily resolved through enrollment in the Illinois Breast and Cervical Cancer Program (IBCCP; ref. 30). IBCCP is a federal-state grant program that offers free screening, diagnostic testing, and treatment to eligible women (31). All CCNP navigators received special training to enroll their uninsured patients into IBCCP.

Research suggests that screening test modality (ref. 18; abnormal mammogram vs. abnormal CBE for breast cancer) and seriousness (19–21) of abnormal breast and cervical findings are positively associated with adherence rate and timeliness of follow-up. In our study, women eligible due to an abnormal mammogram or an abnormal ultrasound had longer time to breast cancer diagnostic resolution compared with women eligible due to CBE. Contrary to our findings, earlier evaluations of the NBCCEDP revealed that women with abnormal mammograms had shorter time to diagnostic resolution than women with abnormal CBE(s) and normal mammograms (18). According to these investigators, longer diagnostic intervals for an abnormal CBE and a normal mammogram were possibly due to a false sense of security that both women and their providers may have when a mammogram is read as normal and that may delay achieving diagnostic resolution. Consistent with our findings, subsequent studies evaluating NBCCEDP (32, 33) showed that adding case management services reduced median diagnostic interval among women who had a normal mammogram and abnormal CBE.

The most significant limitation is the quasi-experimental nature of our study, which makes it difficult to rule out other confounding factors. Also, data for controls were obtained from medical chart reviews, and hence our research was restricted to data elements that are usually collected in the medical chart, such as the basic demographics of patient. To reduce biases, we included covariates and random effects site adjustments. However, some of the differences in results between the navigated and control arms may be due to factors such as educational attainment and income, which were not recorded in patients' medical charts. We are somewhat reassured by the fact that navigated and control cases were recruited from comparable clinic sites and we would not expect that educational attainment or income of navigated and control cases would differ appreciably. Furthermore, we detect a positive navigation effect even though the navigation groups were arguably more disadvantaged than the control groups. For example, compared with controls, a higher percentage of navigated subjects were uninsured in the breast cancer study arm (84% vs. 59%) and were publicly insured in the navigated cervical cancer arm (52% vs. 40%). We would expect that uninsured and publicly insured patients face more obstacles and would fare worse than privately insured patients in receiving timely cancer care (5, 6). However, the navigated patients did better than the control patients despite their greater vulnerabilities. Another important limitation related to our study design is the lack of generalizability of our findings to health care facilities beyond the ones included in our study. Another unique operational feature of our program is having assured financial access to follow-up care after an abnormal screen through IBCCP services for all program participants, regardless of income. Because of the complex nature of the health care delivery system, we were not able to track the receipt of services outside the program such that participants who received diagnostic resolution outside the program were possibly misclassified as unresolved. Finally, all PNRP projects have operationalized navigation in the same way and have targeted populations at greater risk of disparate cancer outcomes. However, a limitation is that different study designs were used to test PN efficacy (14).

Despite significant efforts invested at local, state, and federal levels to alleviate disparities in breast and cervical cancer outcomes, research persistently documents disparities in cancer care and outcomes that are associated with race/ethnicity (1, 5, 34, 35) and SES (5, 36). There is evidence suggesting the effectiveness of NBCCEDP to facilitate timely follow-up after abnormal breast cancer screening (32). However, due to limited funding, NBCCEDP services reach only 12% to 15% of the eligible breast and cervical cancer population (37, 38), and there remains a substantial need for services for underserved populations. PN aims to alleviate disparities in cancer outcomes that are due to barriers for obtaining cancer care. Our data suggest that PN is efficacious in increasing the proportion of patients who achieve timely breast and cervical diagnostic resolution.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Authors' Contributions

Conception and design: E.A. Clahoun
Development of methodology: E.A. Clahoun
Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): E.A. Clahoun

Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): T.W. Markossian, J.S. Darnell, E.A. Clahoun
Writing, review, and/or revision of the manuscript: T.W. Markossian, J.S. Darnell, E.A. Clahoun
Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases): T.W. Markossian, E.A. Clahoun
Study supervision: E.A. Clahoun

Acknowledgments

The authors thank the National Cancer Institute for funding this project. The authors also wish to thank Milton Eder and Julia Shklovskaya at ACCESS for their support in data collection; Sally Freels for advising and reviewing the statistical analysis; and Karen Freund, Electra Paskett, Michael Pennell, Peter Raich, and Kristen Wells from PNRP who reviewed earlier drafts of the manuscript. The authors particularly thank the patient navigators and research assistants of the CCNP whose dedicated efforts have made this project possible.

Grant Support

This research was supported by the National Cancer Institute grant 1 U01 CA116875-01.

Received May 1, 2012; revised August 20, 2012; accepted August 22, 2012; published online October 8, 2012.

References

1. Siegel R, Ward E, Brawley O, Jemal A. Cancer statistics, 2011: the impact of eliminating socioeconomic and racial disparities on premature cancer deaths. CA Cancer J Clin 2011;61:212–36.
2. Anderson WF, Jatoi I, Devesa SS. Assessing the impact of screening mammography: breast cancer incidence and mortality rates in Connecticut (1943–2002). Breast Cancer Res Treat 2006;99:333–40.
3. Tabar L, Yen MF, Vitak B, Chen HH, Smith RA, Duffy SW. Mammography service screening and mortality in breast cancer patients: 20-year follow-up before and after introduction of screening. Lancet 2003;361:1405–10.
4. Surveillance Epidemiology and End Results (SEER) Program. Cancer Statistics Review. Bethesda, MD: National Cancer Institute; 2009.
5. Mandelblatt JS, Yabroff KR, Kerner JF. Equitable access to cancer services: a review of barriers to quality care. Cancer 1999;86:2378–90.
6. Yabroff KR, Washington KS, Leader A, Neilson E, Mandelblatt J. Is the promise of cancer-screening programs being compromised? Quality of follow-up care after abnormal screening results. Med Care Res Rev 2003;60:294–331.
7. National Healthcare Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; 2009.
8. Cancer facts and figures 2011. Atlanta, GA: American Cancer Society; 2011.
9. Cancer and the poor: a report to the nation. Atlanta, GA: American Cancer Society (ACS); 1989.
10. Freund KM, Battaglia TA, Calhoun E, Dudley DJ, Fiscella K, Paskett E, et al. National Cancer Institute Patient Navigation Research Program: methods, protocol, and measures. Cancer 2008;113:3391–9.
11. Battaglia TA, Burhansstipanov L, Murrell SS, Dwyer AJ, Caron AS. Assessing the impact of patient navigation: prevention and early detection metrics. Cancer 2011;117:3553–64.
12. Paskett ED, Harrop JP, Wells KJ. Patient navigation: an update on the state of the science. CA Cancer J Clin 2011;61:237–49.
13. Wells KJ, Battaglia TA, Dudley DJ, Garcia R, Greene A, Calhoun E, et al. Patient navigation: state of the art or is it science? Cancer 2008;113:1999–2010.
14. Roetzheim RG, Freund KM, Corle DK, Murray DM, Snyder FR, Kronman AC, et al. Analysis of combined data from heterogeneous study designs: an applied example from the patient navigation research program. Clin Trials. 2012;9:176–87.
15. Longest BB YG. Coordination and Communication. In:Shortell SK KA, editor. Health care management: organization design and behavior. 4th ed. Albany, NY: Delmar Publishers 2000. p. 237–75.
16. Calhoun EA, Whitley EM, Esparza A, Ness E, Greene A, Garcia R, et al. A national patient navigator training program. Health Promot Pract 2010;11:205–15.
17. Centers for Disease Control and Prevention. National Breast and Cervical Cancer Early Detection Program Program Manual. Policy and Procedure Chapter; 2005 [cited 2010 December]. Available from: http://www.pacificcancer.org/cancer-information/breast-manager.html
18. Caplan LS, May DS, Richardson LC. Time to diagnosis and treatment of breast cancer: results from the National Breast and Cervical Cancer Early Detection Program, 1991–1995. Am J Public Health 2000;90:130–4.
19. Fox P, Amsberger P, Zhang X. An examination of differential follow-up rates in cervical cancer screening. J Community Health 1997;22:199–209.
20. Haas JS, Cook EF, Puopolo AL, Burstin HR, Brennan TA. Differences in the quality of care for women with an abnormal mammogram or breast complaint. J Gen Intern Med 2000;15:321–8.
21. Tabnak F, Muller HG, Wang JL, Zhang W, Howell LP. Timeliness and follow-up patterns of cervical cancer detection in a cohort of medically underserved California women. Cancer Causes Control 2010;21:411–20.
22. Barrett RE, Cho YI, Weaver KE, Ryu K, Campbell RT, Dolecek TA, et al. Neighborhood change and distant metastasis at diagnosis of breast cancer. Ann Epidemiol 2008;18:43–7.
23. McLafferty S, Wang F. Rural reversal? Rural-urban disparities in late-stage cancer risk in Illinois. Cancer 2009;115:2755–64.
24. Abe T, Martin IB, Roche LM. Clusters of census tracts with high proportions of men with distant-stage prostate cancer incidence in New Jersey, 1995 to 1999. Am J Prev Med 2006;30:S60–6.
25. Barry J, Breen N. The importance of place of residence in predicting late-stage diagnosis of breast or cervical cancer. Health Place 2005;11:15–29.
26. Bradley CJ, Given CW, Roberts C. Race, socioeconomic status, and breast cancer treatment and survival. J Natl Cancer Inst 2002;94:490–6.
27. Lacey L, Whitfield J, DeWhite W, Ansell D, Whitman S, Chen E, et al. Referral adherence in an inner city breast and cervical cancer screening program. Cancer 1993;72:950–5.
28. Battaglia TA, Santana MC, Bak S, Gokhale M, Lash TL, Ash AS, et al. Predictors of timely follow-up after abnormal cancer screening among women seeking care at urban community health centers. Cancer 2010;116:913–21.
29. Hiatt RA, Pasick RJ, Stewart S, Bloom J, Davis P, Gardiner P, et al. Community-based cancer screening for underserved women: design and baseline findings from the Breast and Cervical Cancer Intervention Study. Prev Med 2001;33:190–203.
30. Tejeda S, Darnell JS, Cho YI, Stolley MR, Markossian TW, Adegboro OS, et al. Patient barriers to follow-up care for breast and cervical abnormalities. In-preparation
31. About the Illinois Breast and Cervical Cancer Program. [cited 2012 Jul 01]. Available from: http://cancerscreening.illinois.gov/
32. Lobb R, Allen JD, Emmons KM, Ayanian JZ. Timely care after an abnormal mammogram among low-income women in a public breast cancer screening program. Arch Intern Med 2010;170:521–8.
33. Richardson LC, Royalty J, Howe W, Helsel W, Kammerer W, Benard VB. Timeliness of breast cancer diagnosis and initiation of treatment in the National Breast and Cervical Cancer Early Detection Program, 1996–2005. Am J Public Health 2010;100:1769–76.
34. Jacobellis J, Cutter G. Mammography screening and differences in stage of disease by race/ethnicity. Am J Public Health 2002;92:1144–50.
35. Menashe I, Anderson WF, Jatoi I, Rosenberg PS. Underlying causes of the black-white racial disparity in breast cancer mortality: a population-based analysis. J Natl Cancer Inst 2009;101:993–1000.

36. Byers TE, Wolf HJ, Bauer KR, Bolick-Aldrich S, Chen VW, Finch JL, et al. The impact of socioeconomic status on survival after cancer in the United States: findings from the National Program of Cancer Registries Patterns of Care Study. Cancer 2008;113:582–91.
37. Tangka FK, Dalaker J, Chattopadhyay SK, Gardner JG, Royalty J, Hall IJ, et al. Meeting the mammography screening needs of underserved women: the performance of the National Breast and Cervical Cancer Early Detection Program in 2002–2003 (United States). Cancer Causes Control 2006;17:1145–54.
38. Chattopadhyay SK, Hall HI, Wolf RB, Custer WS. Sources of health insurance in the U.S.: analysis of state-level data and implications for public health programs. J Public Health Manag Pract 1999;5:35–46.

Follow-Up and Timeliness After an Abnormal Cancer Screening Among Underserved, Urban Women in a Patient Navigation Program

Talar W. Markossian, Julie S. Darnell and Elizabeth A. Calhoun

Cancer Epidemiol Biomarkers Prev 2012;21:1691-1700.