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Navigating Latinas With Breast Screen Abnormalities to Diagnosis:

The Six Cities Study

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Abstract

BACKGROUND—Breast cancer is the leading cause of cancer-related deaths in Latinas, chiefly because of later diagnosis. The time from screening to diagnosis is critical to optimizing cancer care, yet the efficacy of navigation in reducing it is insufficiently documented. Here, the authors evaluate a culturally sensitive patient navigation program to reduce the time to diagnosis and increase the proportions of women diagnosed within 30 days and 60 days.

METHODS—The authors analyzed 425 Latinas who had Breast Imaging Reporting and Data System (BI-RADS) radiologic abnormalities categorized as BI-RADS-3, BI-RADS-4, or BI-RADS-5 from July 2008 to January 2011. There were 217 women in the navigated group and 208 women in the control group. Women were navigated by locally trained navigators or were not navigated (data for this group were abstracted from charts). The Kaplan-Meier method, Cox proportional hazards regression, and logistic regression were used to determine differences between groups.

RESULTS—The time to diagnosis was shorter in the navigated group (mean, 32.5 days vs 44.6 days in the control group; hazard ratio, 1.32; $P = .007$). Stratified analysis revealed that navigation significantly shortened the time to diagnosis among women who had BI-RADS-3 radiologic abnormalities (mean, 21.3 days vs 63.0 days; hazard ratio, 2.42; $P < .001$) but not among those who had BI-RADS-4 or BI-RADS-5 radiologic abnormalities (mean, 37.6 days vs 36.9 days; hazard ratio, 0.98; $P = .989$). Timely diagnosis occurred more frequently among navigated Latinas (within 30 days: 67.3% vs 57.7%; $P = .045$; within 60 days: 86.2% vs 78.4%; $P = .023$). This was

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driven by the BI-RADS-3 strata (within 30 days: 83.6% vs 50%; $P < .001$; within 60 days: 94.5% vs 67.2%; $P < .001$). A lack of missed appointments was associated with timely diagnosis.

CONCLUSIONS—Patient-centered navigation to assist Latina women with abnormal screening mammograms appeared to reduced the time to diagnosis and increase rates of timely diagnosis overall. However, in stratified analyses, only navigated Latinas with an initial BI-RADS-3 screen benefited, probably because of a reduction in missed diagnostic appointments.

Keywords

breast cancer; patient navigation; health disparities; Latinas; Breast Imaging Reporting and Data System; BI-RADS

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among Latinas with an estimated 14,200 diagnosed in 2009.[1] Since 1997, incidence has decreased 1.5% per year among non-Latino white (NLW) women but only 0.9% per year among Latinas.[1] Approximately 2,200 Latinas died from breast cancer in 2009.[2] It is the leading cause of cancer death in Latinas, who are more likely to die of diagnosed breast cancer than NLW women,[3] because breast cancer is diagnosed later in Latinas than NLW women. From 2002 to 2006, 55% of Latina breast cancers were diagnosed at the local stage, compared with 63% of NLW breast cancers.[4] Additional observations suggest that this is accompanied by larger tumors in Latinas.[5,6] Differences are linked to cultural factors, resulting in delayed screening and follow-up.[2,7] Studies have demonstrated that 90-day diagnostic delays—frequently experienced by Latinos and other minorities—reduce survival rates among patients with cancer.[8–10] This is an important cancer health disparity.[11]

When this disparity is controlled in analyses, Latinas remain approximately 20% less likely to survive breast cancer than NLW women.[12] Differences again are associated with cultural and socioeconomic factors that marginalize Latinas and other minorities from cancer care. Language barriers, Breast Imaging Reporting and Data System (BI-RADS) category assigned to the mammogram, insurance status, and other difficulties contribute to suboptimal use of cancer care services.[7,13,14] This is significant, because Latinos are currently the largest US minority and, by 2030, will constitute an estimated 33% of the nation's population.[15,16] Fueled by psychosocial, linguistic, and other sociocultural barriers, disparities translate into increasingly larger gaps in access to care along the entire cancer care continuum.[17,18]

A significant component of these gaps involves the time from abnormal breast screening to diagnosis. Uninsured or underinsured and racial/ethnic minorities often have the longest delays,[7,19,20] particularly involving ambiguous screening results.[21,22] The literature is limited in Latino cultural focus, consistency in reported outcomes, and small or single-site samples. To address this problem, the federally funded "Redes En Accion: The National Latino Cancer Research Network" tested a culturally tailored patient navigation (PN) intervention model, the Six Cities Patient Navigation Study. On the basis of Harold Freeman's successful navigation model,[23] we used trained, bilingual community health workers to assist Latinas in using cancer care services in cities with significant Latino populations (San Francisco, San Diego, New York City, Miami, Houston, and San Antonio, Texas). Study leaders in San Antonio and regional partners in 5 other cities applied findings from previous studies to develop a tailored PN program for Latina women to evaluate its effect on the time from initial abnormal breast screen to the time of diagnosis compared with non-navigated women.[24,25] We hypothesized that navigation would reduce the time from

initial abnormal breast screening to diagnosis and would increase rates of timely diagnosis within 30 days or 60 days of an initial abnormal screen compared with standard care.

MATERIALS AND METHODS

Study Design and Participants

We used a quasiexperimental design to compare unmatched control participants and intervention participants on the time from abnormal breast screening to diagnosis and the proportions diagnosed within 30 days and 60 days of the initial screen in a multisite study of 480 Latinas (n = 251 navigated; n = 229 non-navigated controls). Data were collected by face-to-face interviews (at baseline) and medical charts (follow-up) among navigated women and medical chart review among non-navigated women in 1 community-based clinic at each site. Clinics were associated with a public health department or an academic medical center. The institutional review boards or equivalent oversight bodies at each of the Six Cities Study sites and each participating community health clinic reviewed and approved this study, including informed consent.

A convenience sampling approach was used to recruit participants. Eligibility criteria targeted 480 self-identified Latinas at community-based health clinics, aged ≥18 years with an abnormal breast screening mammogram resulting in a BI-RADS-3 (“probably benign”), BI-RADS-4 (“suspicious”), or BI-RADS-5 (“highly suggestive of malignancy”) result between January 2008 and January 2011. We excluded women who had a history of cancer treated within the last 5 years on the basis that these women may have had prior experience with the complex cancer treatment system and likely would need less navigation intervention. We also excluded those who had experienced past navigation after an abnormal screening because of the potential for confounding. Pregnant women were not specifically recruited but were not excluded from eligibility.

Controls were chosen by determining eligibility consecutively backward from the study start date. Navigated women were identified from the same clinics by determining eligibility consecutively forward. Individuals in the control group received usual treatment, whereas individuals in the intervention group received usual treatment plus patient navigation. Participants overwhelmingly preferred to speak Spanish and had similar low levels of socioeconomic status, age, employment, marital status, and country of origin.

Navigation

PN was adapted from the Freeman and Rodriguez 4-part case management model.[23] Six bilingual Latina patient navigators were used. They all were women ages 25 to 47 years with at least a high school diploma or college degree. In addition, they were trained to coordinate care for those referred for diagnostic evaluation according to our adaptation of the Freeman and Rodriguez model.[23] PN generally began 1 week or sooner after the index abnormal screening examination and continued through diagnosis. Navigators emphasized adherence to diagnostic and treatment plans and also influenced patient behavior through effective communication, education, rapport building, and empathy. These techniques were used to assist in overcoming potential barriers, such as lack of transportation and/or child care, inadequate communication with health care providers, insurance coverage issues, fear of test results and other detriments to care. The patient navigators provided culturally sensitive support and guidance to facilitate diagnosis and care; and they also tracked patient demographics and other information, addressing barriers by negotiating, coordinating, and/or providing resources like transportation, support, and advice and serving as an advocate and liaison. PN time was invariant between navigators but varied with individual needs, ranging from 8 minutes to 30 hours and averaging 3.0 ± 5.2 hours (median = 1.1 hour).

Data

The study began in January 2008. Data were collected through a combination of baseline interviews and/or chart abstraction (for navigated women) or retrospective chart abstraction for non-navigated controls. Project coordinators at each site reviewed data abstraction forms and interview records for completeness, accuracy, and internal consistency. Data were then entered into a secure, password- protected database.

Outcomes

Our primary outcomes were the number of days from index screening abnormality to diagnosis and the proportion of women achieving timely diagnosis (within 30 days or 60 days). The index screening abnormality was determined as the latest date of screening abnormality before the commencement of the diagnostic process.[26] The date of diagnosis was determined as the date of definitive tissue diagnosis (biopsy with pathology report) or clinical evaluation indicating no further need for diagnostic evaluation.[27] Timely diagnosis was calculated as occurring within 30 days or 60 days from an index abnormality. Because studies have indicated that periods of as few as 90 days from the detection of a breast abnormality to the completion of treatment have clinical significance,[28,29] we chose these periods as optimal indicators of timely diagnosis.

Independent Measures

Most independent variables were used as asked. Age was calculated from birth month and year to the date of the abnormal screening test and was categorized as ages <35 years, 36 to 49 years, 50 to 69 years, and ≥70 years. Site was coded corresponding to the name of the city in which the referring clinic was located. BI-RADS classification of screening mammograms is based on BI-RADS criteria.[30] Missed appointments and the presence of comorbidities were collapsed to “0,” reflecting “none,” versus “1 or more.”

Analysis

Analyses were conducted using the SPSS statistical software package (version 19.0; SPSS Inc., Chicago, Ill). We calculated descriptive statistics of group characteristics using chi-square tests, *t* tests, or log-rank tests, as appropriate. Second, we compared the overall time to diagnosis between navigated participants and control participants using the Kaplan-Meier method and determined mediators associated with time using multivariate Cox regression. Although our follow-up was 365 days (to permit continued navigation beyond diagnosis through treatment, for example), we observed that only 9 participants were diagnosed beyond 180 days. These women were censored beyond that time but were included in proportions of women who had a “timely diagnosis” as undiagnosed in those periods. Other studies of breast cancer diagnosis indicate that this exceeds an adequate follow-up period regarding clinical significance.[10,31] On the basis of the initial results, we stratified our initial time-to-diagnosis measure for navigated and control participants according to BI-RADS category, which was the only independent measure associated with the dependent variable other than navigation. We calculated *P* values overall and within BI-RADS categories using Cox regression, in which larger hazards ratios (HRs) indicate a faster time to diagnosis. Next, univariate and multivariate odds ratios (ORs)[32] were generated to test the association of each characteristic with timely diagnosis within 30 days and 60 days.[33] In this analysis, larger ORs indicate greater likelihood of a timely diagnosis. A 2-sided *P* value < .05 indicated statistical significance.

RESULTS

Among 480 women who had initial results categorized as BI-RADS-3, BI-RADS-4, or BI-RADS-5, follow-up data were available for 425 women (88.5%) (Table 1). All participants were seen by a primary care clinician in community- based clinics, indicating that, generally, they were uninsured or publicly insured. Rates of missing dates and/or diagnostic status as well as demographic characteristics were invariant between navigated and control participants. In Figure 1, "overall" indicates that the time to diagnosis appears to be lower overall in the navigated group relative to the control group (median, 20 days vs 27 days; HR, 1.32; 95% CI, 1.08–1.62; $P = .007$). Figure 1 ("BI-RADS-3" and "BI-RADS-4/5") indicates that the time to diagnosis was significantly shorter only among navigated women with a BI-RADS-3 screening result (median, 9 days vs 40 days; HR, 2.42; 95% CI, 1.63–3.59; $P < .001$). Subsequent Cox regression analysis revealed that only the number of missed appointments was associated with the time to diagnosis (Table 2).

In addition, navigated women achieved timely diagnosis significantly more often than women in the control group (30 days: 67.3% vs 57.7%, respectively; $P = .045$; 60 days: 86.2% vs 78.4%, respectively; $P = .023$) (Table 3). However, this effect occurred only among women who had an initial BI-RADS-3 screening result (30 days: 83.6% vs 50%, respectively; $P < .001$; 60 days: 94.5% vs 67.2%, respectively; $P < .001$). There was no comparable difference among women who had initial BI-RADS-4/5 screening result. Like the time-to-diagnosis analysis, the number of missed appointments was the only significant predictor of a timely diagnosis (Table 4).

DISCUSSION

Time to Diagnosis and Timely Diagnosis Among Navigated Latinas

To our knowledge, this is the first study of Latinas to consider the effect of PN on the time to diagnosis and to stratify those results by the type of initial abnormal screen. In this study, approximately 33% of eligible women had screening results categorized as BI-RADS-3, and the impact of navigating BI-RADS-3 women indicates that they are diagnosed significantly faster than comparable non-navigated women. The finding that this occurs and caused by fewer missed appointments and a more rapid diagnostic confirmation lends support to efforts at reducing the BI-RADS-3 classification to a less threatening BIRADS result,[22,34] and it has been observed that women literally "suffer" through a BI-RADS-3 result while awaiting diagnosis.[32,35] The current study provides strong implications that navigated Latinas who had a BI-RADS-3 screening result probably were relieved of the burden of worry about their abnormal result.

Patient Navigation: Great Expectations

Studies have demonstrated repeatedly that cancer places an unequal burden on patients with lower socioeconomic status and on racial/ethnic minority women.[19,20,36,37] These disparities manifest themselves in lower survival rates among disadvantaged women, and it has been demonstrated that they are the consequence of a sequence of circumstances, including minority status and marginalization, inability to access and adequately use medical resources, unavailability of those resources in some locales, late diagnoses and more severe disease, and similar delays in treatment, ultimately leading to higher rates of death.[38,39] Disparities must be ameliorated, and PN may provide an effective intervention to accomplish this.

PN programs are increasing in the United States despite the lack of empiric evidence for their efficacy or cost-effectiveness.[40] The expected impact of PN on some aspects of the cancer care continuum is high, but demonstrating efficacy has been difficult. Evidence was

summarized in a recent review, which noted the rapid expansion of PN while underscoring study limitations, including lack of randomization, absence of control groups, small sample sizes, and inability to compare endpoints.[41] Although the benefits of applying PN to the barriers faced by low-income, underserved minority groups in dealing with cancer remains unclear, there is some evidence that PN works when applied correctly and in a timely fashion to specific clinical challenges.[23] Simultaneously, there is little evidence that we have generally identified those specific challenges and how PN mediates them.[40] Therefore, it is difficult to know when, where, and how to apply PN. In the current article, we report 1 successful application of PN to a limited target group (Latinas with a BI-RADS-3 result).

Secular Trends in Screening and Diagnosis and an Unexpected Finding

PN appears to be a specific, rather than general, curative for disparities. Our results indicate an overall decrease in the time to diagnosis between navigated and non-navigated women caused almost exclusively by a decrease in time among women with an initial BI-RADS-3 screen. This may be because secular trends in diagnosing breast cancer among women at some clinics have improved (as in the Mayo Clinic Center for Excellence in Breast Cancer),[39] especially when the probable risk of cancer is considered relatively high (eg, BI-RADS-4 or BI-RADS-5). Little further improvement is gained by navigating all women from abnormal screening to diagnosis. Women with an abnormal result of BI-RADS-3, however, may fall into a nosological “no-man’s land” of relative less importance—the likelihood of cancer in a woman with a BI-RADS- 3 screening result is approximately 2% to 4%.[38] This is an unexpected finding: Although we did not design the study to compare the time to diagnosis between BI-RADS groups within the navigated and control arms, the time to diagnosis with the navigation group went from 9 days for those with BI-RADS-3 results to 26 days for those with BI-RADS-4/5 results. This suggests that women who are informed that their screening mammogram is “abnormal” (albeit with a low likelihood of cancer) are 1 group for whom PN, problematically, is appropriate. On the basis of this finding, PN is likely to have a very small impact on breast cancer morbidity and mortality outcomes (ie, if only 2%–4% of BI-RADS-3 women have cancer, then reducing the time to diagnosis will have a very minor population impact on early diagnosis of breast cancer). However, it may have a major impact on addressing Latinas’ anxiety associated with abnormal results. Further studies will be required to evaluate these results.

In conclusion, patient-centered navigation to assist Latina women with breast screening abnormalities reduces the time to diagnosis by nearly 66% among Latina women with an initial BI-RADS-3 classification compared with non-navigated controls. Moreover, this reduction is reflected in increases in rates of timely diagnosis within 30 and 60 days if an initial screening abnormality is classified within a range in which the likelihood of cancer is between 2% and 4% (BI-RADS-3). Navigation appears to assist Latinas who have an initial BI-RADS-3 abnormal mammogram in reducing missed follow-up appointments, but not Latinas who have a greater likelihood of a cancer diagnosis.

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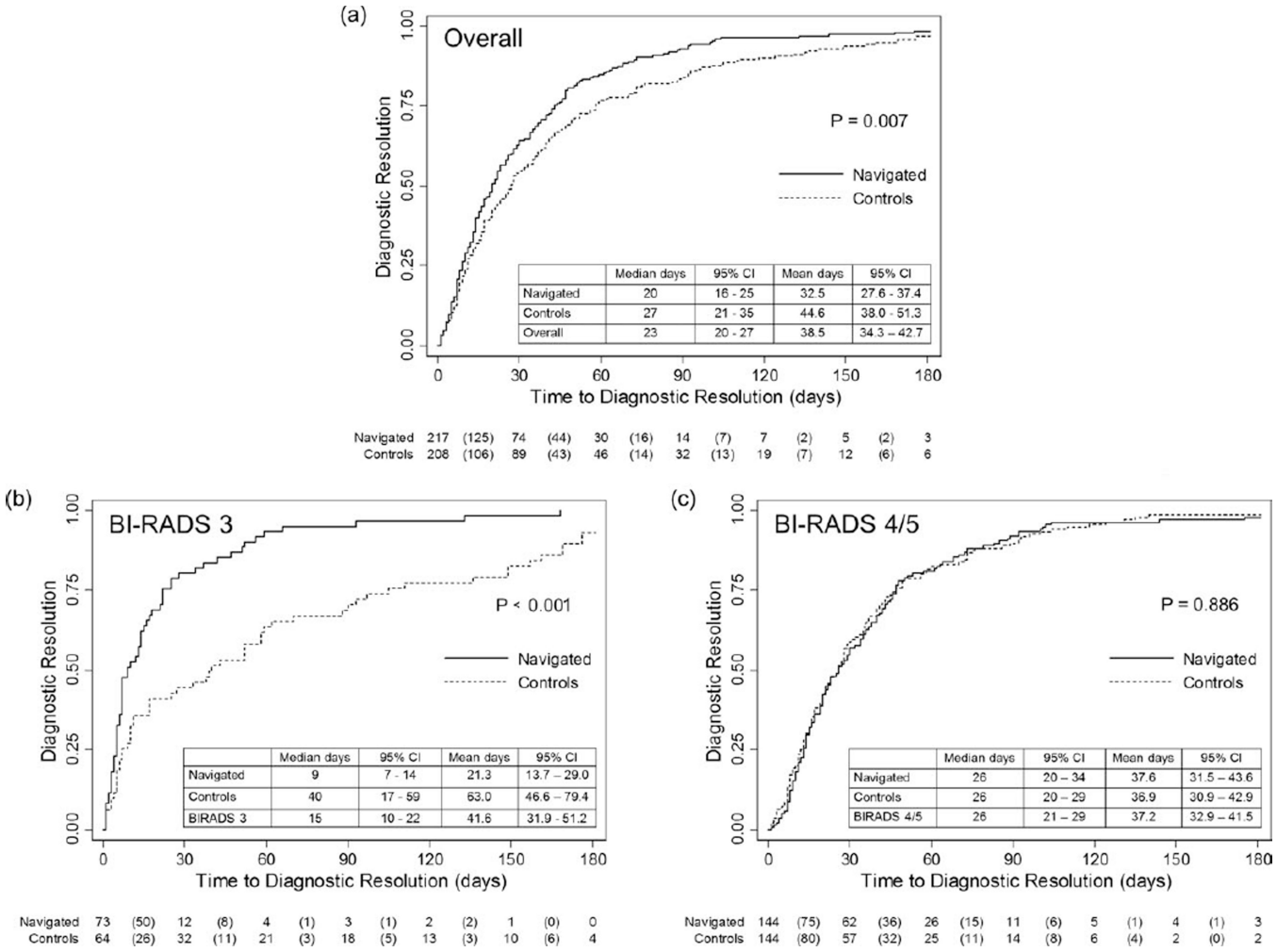

Figure 1.

Kaplan-Meir time-to-diagnosis comparison, navigated versus control subjects, overall and stratified by BI-RADS. Censored at 180 days.

TABLE 1

Demographic Characteristics of Women in the Navigated and Control Groups

Measure	No. of Patients (%)[a]		
	Control Group, N = 208	Navigated Group, N = 217	Total, N = 425
Site[b]			
A	41 (19.7)	33 (15.2)	74 (17.4)
B	19 (9.1)	18 (8.3)	37 (8.7)
C	43 (20.7)	50 (23)	93 (21.9)
D	38 (18.3)	30 (13.8)	68 (16)
E	25 (12)	41 (18.9)	66 (15.5)
F	42 (20.2)	45 (20.7)	87 (20.5)
Age category, y			
<35	10 (4.8)	17 (10.3)	27 (7.3)
36–49	75 (36.2)	56 (33.9)	131 (35.2)
50–69	111 (53.6)	91 (55.2)	202 (54.3)
≥70	11 (5.3)	1 (0.6)	12 (3.2)
Country of origin			
US	12 (17.4)	53 (25.5)	62 (22.6)
Mexico	14 (20.3)	78 (37.5)	92 (33.6)
Other	43 (62.3)	77 (37)	120 (43.8)
Marital status			
Married/living as married	85 (42.1)	86 (42.2)	171 (42.3)
Unmarried	117 (57.9)	116 (57.6)	233 (57.7)
Employment status			
Yes	40 (36)	89 (42.2)	129 (40.1)
No	71 (64)	122 (57.8)	193 (59.9)
Insurance status			
Medicare	16 (7.8)	16 (7.7)	32 (7.7)
Private insurance	39 (18.9)	37 (17.8)	76 (18.4)
Other local government payment-assistance plan	67 (32.5)	65 (31.3)	132 (31.9)
None	84 (40.8)	90 (43.3)	174 (42)
BI-RADS category			
BI-RADS-3	64 (30.8)	73 (33.6)	137 (32.2)
BI-RADS-4	114 (54.8)	126 (58.1)	240 (56.5)
BI-RADS-5	30 (14.4)	18 (8.3)	48 (11.3)
Missed appointments			
None	164 (78.8)	179 (82.5)	343 (80.7)
≥1	44 (21.2)	38 (17.5)	82 (19.3)
Comorbidity[c]			
No	177 (85.1)	177 (81.6)	354 (83.3)

Measure	No. of Patients (%)[a]		
	Control Group, N = 208	Navigated Group, N = 217	Total, N = 425
Yes	23 (11.1)	20 (9.2)	43 (10.1)

Abbreviations: BI-RADS, Breast Imaging Reporting and Data System.

[a] Sample sizes vary within cells because of missing or unavailable data.

[b] Site names are anonymized in this table.

[c] These include any comorbidity noted on a patient's chart or reported by a patient, including: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease (mild, moderate/severe), diabetes mellitus (with or without complications), hemiplegia or paraplegia, renal disease, and acquired immunodeficiency syndrome.

TABLE 2

Predictors of the Time to Diagnosis for Breast Screening Abnormalities[a]

		95% CI		
Measure	**HR**	**Lower**	**Upper**	***P***
Navigated group	1.41	1.15	1.74	.001
BI-RADS				
Overall[d]				< .001
BI-RADS-3 (referent)[e]	—	—	—	—
BI-RADS-4/5	1.06	0.84	2.61	.801
Covariates[b]				
Missed appointments: None missed vs any missed (referent)	0.47	0.36	0.62	< .001

Abbreviations: BI-RADS, Breast Imaging Reporting and Data System; CI, confidence interval; HR, hazard ratio (from Cox proportional regression analysis); Referent, reference category.

[a]The time to diagnosis is defined as the time in days from date of the initial abnormal examination to the date of diagnosis. Data were censored at 180 days in this analysis. Nine women were censored because their diagnosis occurred >180 days after initial detection of the abnormality. All covariates were tested in the multivariate model, and only those that were associated significantly with the dependent variable are listed.

TABLE 3

The Proportion of Participants With a Timely Diagnosis (Within 30 Days and Within 60 Days of Abnormal Screen) Overall and Stratified by Type of Abnormal Screen[a]

	Diagnosed Within 30 Days		Diagnosed Within 60 Days	
Group	**No. of Women (%)**	***P***	**No. of Women (%)**	***P***
Overall				
Navigated, n = 208	146 (67.3)	.045	187 (86.2)	.023
Controls, n = 217	120 (57.7)		163 (78.4)	
BI-RADS-3				
Navigated, n = 73	61 (83.6)	< .001	69 (94.5)	< .001
Controls, n = 64	32 (50)		43 (67.2)	
BI-RADS-4/5				
Navigated, n = 144	85 (59)	.810	118 (81.9)	.438
Controls, n = 144	88 (61.1)		120 (83.3)	

Abbreviations: BI-RADS, Breast Imaging Reporting and Data System.

[a]Timely diagnosis is defined as a diagnosis within 30 days and 60 days of the initial abnormal screen, as indicated. Nine women who were censored in the survival models were included here as “not diagnosed” (based on intent to treat).

TABLE 4

Predictors of Timely Diagnosis Within 30 Days and 60 Days of Breast Abnormality[a]

	Overall		BIRADS3		BIRADS4/5	
Variable[b]	**OR (95%CI)**	***P***	**OR (95%CI)**	***P***	**OR (95%CI)**	***P***
Diagnosed within 30 d of abnormality						
Navigation						
No	Referent		Referent		Referent	
Yes	1.51 (1.01–2.19)	.049	5.25 (2.36–11.66)	< .001	0.89 (0.56–1.44)	.641
BI-RADS category						
BI-RADS-3	1.42 (0.97–2.20)	.110				
BI-RADS-4/5	Referent					
Missed appointments						
No	Referent		Referent		Referent	
Yes	0.61 (0.42–1.15)	.792	0.57 (0.34–1.21)	.194	0.69 (0.35–1.38)	.296
Diagnosed within 60 d of abnormality						
Navigation						
No	Referent		Referent		Referent	
Yes	1.72 (1.03–2.85)	.038	8.74 (2.78–27.4)	< .001	0.90 (0.49–1.67)	.742
BI-RADS category						
BI-RADS-3	1.41 (0.97–2.22)	.081				
BI-RADS-4/5	Referent					
Missed appointments						
No	Referent		Referent		Referent	
Yes	0.62 (0.32–1.22)	.194	0.51 (0.32–0.99)	.047	0.90 (0.37–2.20)	.827

Abbreviations: BI-RADS, Breast Imaging Reporting and Data System; CI, confidence interval; OR, odds ratio (from multiple logistic regression).

[a]Timely diagnosis is defined as a diagnosis within 30 days or 60 days of initial abnormal screen. Nine women who were censored in the survival models were included here as “not diagnosed” (based on intent to treat).

[b]All potential covariates were tested in multivariate models. Only those associated significantly with the dependent variable are shown.