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Patient Navigation Improves Subsequent Breast Cancer Screening After a Noncancerous Result: Evidence from the Patient Navigation in Medically Underserved Areas Study

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Abstract

Background: Past efforts to assess patient navigation on cancer screening utilization have focused on one-time uptake, which may not be sufficient in the long term. This is partially due to limited resources for in-person, longitudinal patient navigation. We examine the effectiveness of a low-intensity phone- and mail-based navigation on multiple screening episodes with a focus on screening uptake after receiving noncancerous results during a previous screening episode.
Methods: The is a secondary analysis of patients who participated in a randomized controlled patient navigation trial in Chicago. Participants include women referred for a screening mammogram, aged 50–74 years, and with a history of benign/normal screening results. Navigation services focused on identification of barriers and intervention via shared decision-making processes. A multivariable logistic regression intent-to-treat model was used to examine differences in odds of obtaining a screening mammogram within 2 years of the initial mammogram (yes/no) between navigated and non-navigated women. Sensitivity analyses were conducted to explore patterns across subsets of participants (*e.g.*, navigated women successfully contacted before the initial appointment; women receiving care at Hospital C).
Results: The final sample included 2,536 women (741 navigated, 1,795 non-navigated). Navigated women exhibited greater odds of obtaining subsequent screenings relative to women in the standard care group in adjusted models and analyses including women who received navigation before the initial appointment.
Conclusions: Our findings suggest that low-intensity navigation services can improve follow-up screening among women who receive a noncancerous result. Further investigation is needed to confirm navigation's impacts on longitudinal screening.

Keywords: breast health, cancer, quasi-experimental, navigation, repeat screening

Introduction

Advances in cancer prevention and control have resulted in an overall decline in breast cancer mortality rates in the United States.[1,2] Despite these advances, significant racial and socioeconomic disparities in cancer mortality have persisted.[3]

One of the contributing factors of such mortality disparities is differences in early detection. Although there have been recent controversies regarding screening mammography, including when to initiate screening, the age to begin screening, and its effectiveness at reducing mortality,[4,5] screening mammography remains the best evidence-based tool to reduce breast cancer mortality. Several randomized trials have documented that mammography utilization reduces breast cancer mortality rates by 15% to 20%.[6,7]

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Racial/ethnic minority and socioeconomically disadvantaged women are less likely to engage in routine screening,[8,9] which may contribute to greater likelihood of late stage diagnoses[10] and higher mortality rates.[11,12] Improving screening mammography rates among these populations may be an effective strategy to address breast cancer disparities.

Patient navigation is an evidence-based approach to reduce breast cancer disparities through improving screening.[13–17] Wells et al.[18] defined patient navigation by the following characteristics: (1) occurs within a specific cancer care event (*e.g.*, one-time screening); (2) involves longitudinal tracking with a specific endpoint (*e.g.*, a definitive diagnosis); (3) targets the health services that are needed to achieve the endpoint (*e.g.*, screening and/or diagnostic care); (4) addresses individual-level barriers; and (5) aims to reduce delays in cancer care access and uptake. The effectiveness of patient navigation for optimal cancer care uptake is well-documented,[19–21] especially for screening and diagnostic care.[16–18] A systematic review documented increases in screening by 11% to 17% among navigated patients compared with patients receiving standard care.[18] A more recent review documented that, of five studies published between 2010 and 2015, two randomized controlled trials found significantly higher rates of mammography screening among women assigned to navigation (87%–93%) relative to standard care (76%–88%).[16] Together, study arm differences in screening for these more recent studies are somewhat smaller than previous literature (*e.g.*, 5%–11% versus 11%–17%).[18]

A major gap in the current navigation literature is that most studies focused on screening have been cross-sectional or one-time receipt of screening or ecological in nature (*e.g.*, hospital-level screening rates pre- and postnavigation programs).[13,14,16–18] A longitudinal look at navigation is important for screening in particular, given one-time utilization is not a sufficient strategy for improving early detection of breast cancer. However, little is known about the effectiveness of navigation across multiple screening episodes. This may be in part due to high costs associated with in-person navigation. Such ''high-touch'' approaches are effective, but may not be scalable for promoting routine cancer screening, due to high costs and staff burden.[22] Thus, a need exists to examine whether and how alternative, less costly navigation approaches, such as use of phone- and mail-based navigator–patient interactions, may be effective in improving routine screening behavior.

This study is a first step to address this gap. We utilized an existing dataset from a randomized controlled trial that conducted a largely phone and mail-based patient navigation across a 4-year period. The primary outcome of our current analysis is obtaining subsequent screenings after the initial appointment. We operationalized this outcome as attainment of a subsequent screening mammogram within 1–2 years postinitial appointment. Given our interest in longitudinal screening, we focused on women who received noncancerous results from the initial appointment. We hypothesized that navigated women would have greater odds of subsequent screenings compared to women receiving standard care.

Materials and Methods

Parent study

Data for this study are from an individual-level randomized, controlled trial, Patient Navigation in Medically Underserved Areas (PNMUA). During 2011–2014, PNMUA was conducted in three hospitals (''A,'' ''B,'' ''C'') in the South Side of Chicago neighborhoods, which are characterized by high levels of concentrated poverty and racial segregation.[23] Some differences between hospitals existed: Hospital C had a larger patient population; Hospital B and C were sites of two multisite healthcare systems; and, Hospital C was, at the point of the study, a Breast Imaging Center of Excellence. Eight lay health workers living in surrounding communities where the three hospitals were located were hired and trained as navigators (*e.g.*, breast cancer disparities facts; enabling patients to choose from multiple solutions to address barriers)[24,25]

The study was designed to examine the effectiveness of patient navigation on time to diagnostic resolution among adult women referred for a screening or diagnostic mammogram within one of the three hospitals. Overall processes were described in previous work.[24] Primary outcomes included adherence to this initial referral and time to a definitive diagnosis (cancer/not cancer). Randomization processes differed across hospitals, due to patient population size. Specifically, for the parent study, randomization ratios were 1:1 control/navigation for Hospitals A and B, but were 3:1 control/navigation for Hospital C. Type of mammography referral was also incorporated into randomization ratios, such that women referred for diagnostic mammography were more likely to be assigned to navigation than control, while women referred for screening mammography were equally likely to be assigned to either study arm. The overrepresentation of diagnostic cases in navigation and differences in randomization ratio at the hospital level resulted in nonequivalent groups, in that navigated women (overall) were more likely to be older ($p = 0.02$) and more likely to be African American ($p = 0.02$).

The University of Illinois at Chicago Institutional Review Board approved all study protocols and materials.

Current study and sample characteristics

The primary interest, as described above, for this study is longitudinal breast cancer screenings. To note, there is an ongoing debate regarding breast cancer screening[4,5,26] and several guidelines exist (American Cancer Society; National Comprehensive Cancer Network; US Preventive Services Taskforce [USPSTF]).[27–29] Given this, we focus our efforts only on women aged 50–74 years.

Figure 1 depicts the parent study overall and the subset of participants for this study. The majority of women who were excluded from this study (63% of the entire sample) because they were referred for diagnostic mammography ($n = 3,383$), did not have documented age to be eligible for screening mammography according to USPSTF guidelines ($n = 2,356$), or received an abnormal result ($n = 293$). Among the remaining 3,404 women, 254 women did not attend their initial screening mammography appointment and 614 women had missing data on sociodemographic or healthcare-related information. Women in the analytic sample ($n = 2,536$), women who did not attend their initial screening mammography appointment, and women with missing data on sociodemographic or healthcare-related information did not vary with regard to age, income, or driving distance to the facility ($p = 0.49$–0.85). Women in the analytic sample were slightly more likely to have been navigated ($p = 0.08$), were

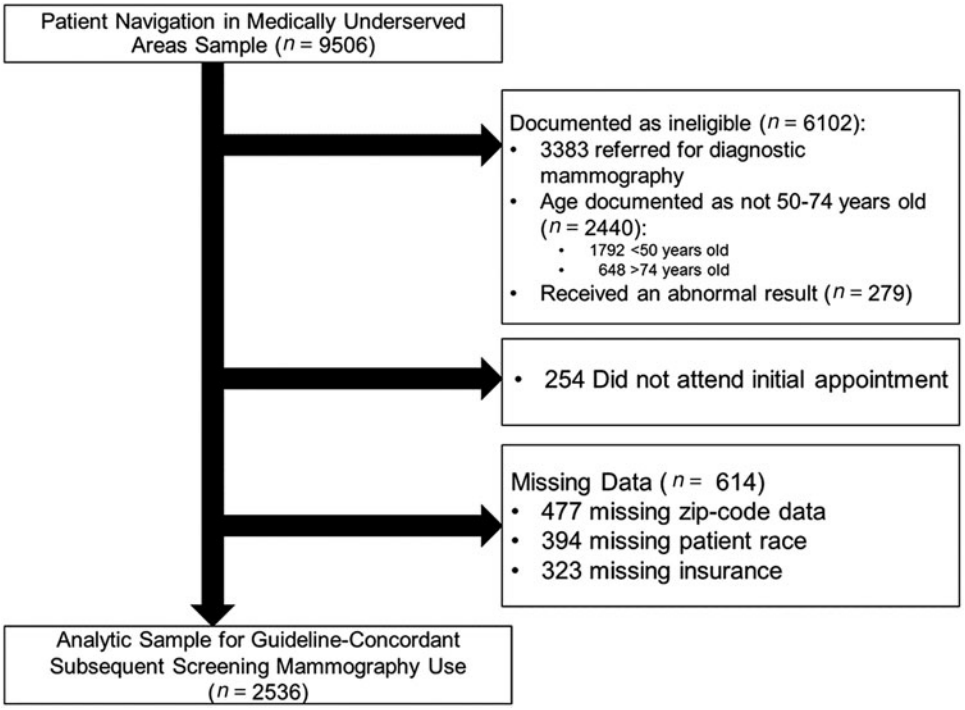

FIG. 1. Diagram of parent study and current study's analytic sample.

significantly more likely to have received services from Hospital C ($p < 0.0001$), and were significantly less likely to be African American ($p = 0.001$) relative to women who did not attend their initial screening mammography appointment, and women with missing data on sociodemographic or healthcare-related information.

Intervention

The following abbreviated description of the intervention pertains to the subsample of asymptomatic, age-eligible women included in this analysis. To note, for both groups, there was a patient-driven referral process. Specifically, patients sought primary care provider referrals for the initial screening and had to seek primary care provider referrals for subsequent screenings. Study staff did not engage primary care providers.

Patient identification and randomization. We employed a postrandomization consent design. Specifically, navigators first identified participants from hospital daily lists of new patients who had been referred for a mammography appointment. Eligible potential participants were assigned into standard care or navigation arms using a computerized randomization program in SAS. Treatment assignment was masked to healthcare providers and investigators.

Standard care. Women randomized into the control arm received usual care and usually did not interact with study staff throughout initial or subsequent breast cancer care. Navigators tracked patient utilization of care through electronic medical record data. Standard care from the radiology departments in the participating hospitals included a mailed reminder within 2 weeks of the scheduled appointment with the date and time of the appointment along with contact information for scheduling purposes. Mailed reminders were given for the initial screening mammogram. For women with normal/benign results, mammography departments entered ''pending'' mammography appointments and mailed women reminders about these subsequent ''pending'' mammography appointments. Pending appointments were only confirmed and scheduled after women contacted their primary care providers for referrals.

Navigation

Contact for initial mammography appointments. For the initial contact, navigators made up to 10 attempts to make phone contact with women randomized to receive navigation before the initial provider-referred screening mammography appointment ($M = 2.13$, SD = 1.97). As depicted in Table 1, 364 (49%) of navigated women were successfully contacted before their initial appointment and received phone-based navigation services before the appointment. During the initial contact, navigators first offered a brief description of the study, obtained informed consent, and completed baseline surveys. In line with the National Cancer Institute (NCI) Patient Navigation Research Program,[15] navigators provided the following services: (1) assessed patients' comprehension of mammography and their specific appointment (*e.g.*, date, time, location, procedures); (2) assisted with clarification for any knowledge barriers; (3) assessed other immediate barriers to attending the appointment (*e.g.*, psychosocial; logistic); and, (4) engaged in shared decision making to develop a plan of action to address. Subsequently, navigators utilized a ''teach back'' method, wherein navigators encouraged patients to report their understanding of the information exchanged and ask questions about their appointments, care options, and selected solutions. With regard to barriers, the most common concerned systemic problems with scheduling care (*e.g.*, issues with mailed information from the hospital), insurance status, work-schedule conflicts, health literacy, transportation, and family/community issues. For these barriers, navigators worked with patients to identify the best

Table 1. Demographic and Healthcare Information by Study Arm (N=2,536)

	Navigated (n=*741*) *M (SD)*	*Standard care* (n=*1,795*) *M (SD)*	p
Neighborhood median household income	$41,034 ($14,561)	$41,102 ($13,939)	0.91
Distance to facility (miles)	4.06 (3.71)	4.14 (3.71)	0.60
	n *(%)*	n *(%)*	
Age, years			
50–59	367 (50)	857 (50)	0.71
60–69	289 (39)	728 (41)	
70–74	85 (12)	210 (12)	
African American race	505 (68)	1,418 (79)	<0.0001
Medicaid/Uninsured	142 (19)	241 (13)	0.001
Hospital C	141 (19)	1,291 (72)	<0.0001
Contacted before initial appointment	364 (49)		
Obtained subsequent screening	381 (51)	829 (46)	0.04

action plan for their specific case (*e.g.*, enrolling in charity care and other resources for un/underinsured women; navigators' translation of hospitals' mailed information). Two days before the appointment, navigators contacted women again to remind them about the appointment and reassess barriers at that time. If phone contact was not possible (n=377), navigators made first contact in person on the day of the appointment. At the end of initial contact (by phone or in person), navigators provided patients with their contact information, in case patients wished to initiate interactions with the navigator in the future (*e.g.*, new emerging barriers).

Contact for subsequent mammography appointments. All navigated women who received normal or benign results from their initial mammogram received mailed reminders 6 months before the date when they had been recommended to schedule appointments. The reminders mailed by navigators included the pending date and time (similar to the standard care reminders), a brief statement encouraging women to engage one's primary care provider for a referral and discuss any issues specific to breast cancer screening, and the contact information for navigators. With regard to barriers, systemic problems with scheduling care (*e.g.*, issues with mailed information from the hospital), insurance status, and health literacy remained the most common barriers. Thus, navigated women received two separate mailed reminders from hospital and study staff relative to women in standard care, who received one reminder from hospital staff. Navigators then called women 2 weeks before scheduled appointments or 2 weeks before the recommended date. Navigators attempted contact for up to 10 times, similar to the initial appointment (M=4.71, SD=3.14). During these calls, navigators used the same methods as those described above to address patient comprehension and barriers via shared decision-making process. Navigators did not interact with primary care providers, although their encouragement for patients to engage primary care providers may have affected overall medical care. Thus, navigated women, like patients receiving standard care, had to seek primary care provider referrals to confirm their ''pending'' appointments at participating hospitals.

Measures

Data for this study were abstracted from women's electronic medical records; survey data, if electronic medical record data were missing; and US Census American Community Survey 2007–2011 data.

Obtaining subsequent screenings was measured as undergoing subsequent screenings after receiving a normal/benign result from the initial mammography appointment (yes=obtaining a subsequent mammogram within 2 years postinitial result; no=not obtaining mammograms every 2 years postinitial result).

Demographic and healthcare information. Medical record data identified which of the three hospital sites participants accessed. A combination of medical record and survey data were used to retrieve participant's age, race/ethnicity, and insurance status. Given participants were predominantly African American (76%), participants were classified as African American or Other for race/ethnicity. Participants were similarly grouped into Hospital C versus A or B, as most participants received care from hospital C. Due to the relatively low number of uninsured women and women with other insurance, participants were classified as having Private insurance, Medicare insurance, or Medicaid/Uninsured. Home addresses from medical records were geocoded to obtain census tract level data concerning neighborhood median income, from the 2007 to 2011 American Community Survey. Distance (miles) to the facility was calculated by Manhattan methods, based on a street network.[30]

Data analysis

We used listwise deletion for the proposed analyses; we describe differences between women in the excluded and analytic sample above. Our analysis plan included multivariable logistic regression models. We used an alpha of 0.05 to determine statistical significance for all analyses. Univariate and bivariate relationships were first assessed. Adjusted analyses to assess differences in recommended subsequent screening mammography use (yes/no) included the following covariates: age, race/ethnicity (African American, Other), health insurance (Private, Medicare, Other), hospital (A/B, C), neighborhood median income, and distance to facility. For all models, standard care participants were the referent group. Finally, we conducted sensitivity analyses. We first repeated analyses among (1) women receiving services at Hospital C, wherein the majority of participants obtained care; and, (2) women who received phone-based navigation

services before initial appointments and women who received standard care.

Results

Table 1 provides the demographic and health insurance information by study arm (741 navigated; 1,795 standard care). Our sample largely received care from Hospital C (56%) and largely identified as African American (76% overall). The neighborhood-level median household income was $41,082. Relative to women in standardized care, navigated women were more likely to have Medicaid insurance or be uninsured, but were less likely to receive care at Hospital C and to be African American.

All subsequent models included demographic (age, race, neighborhood median household income) and healthcare covariates (insurance, site of care, miles to clinic). Navigated women exhibited significantly greater odds of obtaining subsequent screenings relative to women assigned to standard care, adjusted odds ratio (aOR) = 1.25, 95% CI 1.02–1.54, $p = 0.03$. To note, however, the crude difference in proportions of women obtaining subsequent screenings was a modest 5-percentage points (Table 1). Sensitivity models exhibited similar patterns, when we only compared women randomized to standard care to navigated women who were successfully contacted and received phone-based navigation before the initial appointment (46% vs. 56%; $n = 1{,}693$; aOR = 1.47, 95% CI 1.14–1.90, $p = 0.003$). When comparing women who had obtained services at Hospital C, the relationship was attenuated for all navigated women, crude: 45% versus 52%, $n = 1{,}432$, aOR = 1.35, 95% CI 0.95–1.93, $p = 0.09$. Nonetheless, for women receiving care at Hospital C, navigated women who were successfully contacted before initial appointments and received phone-based navigation before the initial appointment had greater odds of subsequent screening relative to women randomized to standard care, 45% versus 59%, $n = 1{,}364$, aOR = 1.75, 95% CI 1.07–2.89, $p = 0.03$.

Discussion

Despite growing controversies,[4,5,26] regular mammography utilization is an effective strategy to reduce delayed diagnosis and consequently mortality of breast cancer.[27,31] Patient navigation is increasingly popular and effective practice to reduce breast cancer disparities.[13–18] this study adds to a growing body of literature concerning its effectiveness by offering some preliminar1y data concerning the receipt of navigation services, especially those administered largely by phone/mail, can be associated with a slight increase in subsequent breast cancer screening after a normal/benign result. Specifically, navigated women had greater odds of obtaining a mammogram 2 years after receiving a noncancerous result on a prior screening mammogram. This is potentially due to the multiple contacts that navigators had with patients, facilitated by using phone and mail modes of intervention delivery.

On the one hand, our findings align with other longitudinal studies concerning navigation's long-term impact on hospitals' breast and colorectal cancer screening rates.[13,14] In particular, our study can be considered preliminary evidence to indicate some long-ranging usefulness of patient navigation particularly relevant for hospitals that have high no-show rates in their mammography clinics. Our sensitivity analyses suggest that, if phone contact before initial appointments is successful, navigation may be particularly useful. Such findings make sense, given these women would have received more intensive navigation and, specifically, navigation services standardized under the NCI Patient Navigation Research Program.[15] That said, the effect was relatively small, similar to that of other recent studies.[16] Further, study arm differences were attenuated when examining all navigated and standard care women receiving care at high-quality facilities/Breast Imaging Centers of Excellence. Simultaneously, this study, due to its phone- and mail-based nature, is less costly. Future studies are warranted to determine differences in effectiveness and costs of different deliveries of patient navigation.

Our study focused on the potential of longitudinal navigation to be effective in promoting screening across multiple episodes. There are benefits to this model, including a consistent relationship of the patient with the same navigator, which may result in greater trust and other protective factors associated with patient adherence, and more consistent tracking of patients in the long term due to a dedicated staff member per patient. Nonetheless, it does rely on the ability of navigators to maintain such a relationship with patients and for relationships to be consistent between navigators, patients, primary care providers, and hospitals. The latter may not be possible for certain vulnerable populations, especially those with limited or irregular healthcare access. An alternative approach would be to have navigation begin separately with each new provider referral/order. This alternative model, which is more akin to other navigation services, would allow more flexibility and accommodate the needs of patients who access services from different providers and hospitals. However, the benefits of a stable relationship between the navigator and patient may not be accrued, especially for sites with high staff turnover. Future research is warranted to examine relative effectiveness of these two approaches, including an assessment of benefits and costs.

This study has several limitations. First, PNMUA was not designed to assess the efficacy of patient navigation across multiple cancer-related episodes. The randomization scheme, as noted above and in Table 1, did not result in equivalent study arms. As well, for the overall study, it should be noted that we did not have a 1:1 randomization ratio for all sites, which may have affected our findings. Given this, our study should be considered quasi-experimental in nature and our findings should be interpreted cautiously. Specifically, our study should not be used to confirm causal relationships, but rather to suggest the need for future studies that are able to study these patterns with more rigorous designs. Future randomized controlled trials are specifically needed that have randomization schemes designed to test this research question directly. Due to our study's focus on subsequent screenings among asymptomatic women, we did not include women who did not attend the initial mammography appointment. This was largely due to our inability to confirm that they would have been asymptomatic—we do not specifically know whether they would have received a normal result and been recommended a screening 2 years after the result. We further do not know how the lack of successful contact before the initial appointment (phone) or on the day itself (in person) may have affected their breast cancer care

uptake. Our eligibility criteria included all women who had received a primary care provider referral for a mammogram. However, our study did not capture information concerning whether the provider made this recommendation because women were overdue for a mammogram. This makes it difficult to control for previous screening pattern. Further, our study included only women who had access to primary care (*e.g.*, eligibility criteria for a provider referral). Relatedly, our project relied on a patient-driven referral process; we were not, however, able to collect data concerning interactions with primary care providers. Thus, we are not able to assess the extent to which our findings reflect navigated women having greater odds of obtaining primary care provider referrals versus attending scheduled visits at hospital sites. Further, we were not able to assess whether and how navigation, which did encourage interactions with primary care providers, may have altered overall/general medical care uptake. Overall, even though we adjusted for some potential demographic and healthcare determinants of health, we were unable to adjust for other potential correlates of screening mammography utilization, including screening mammography history, co-morbidity status, and individual-level socioeconomic status indicators. Consequently, our findings may have limited generalizability. Our sample did not allow for powered analyses to examine some important variables in depth, including race/ethnicity. For example, we did not have the statistical power to examine whether patient navigation services reduced or eliminated White-African American disparities in breast cancer-related care. We were unable to obtain data concerning women's mammography utilization outside of the three participating hospitals. Thus, women who may have obtained mammograms within 1–2 years after initial results from other healthcare systems (*e.g.*, due to moving location; changed healthcare insurance) would be misclassified. Our analyses are thus not able to disentangle if navigation services are associated with improved longitudinal screening versus greater utilization of a specific healthcare system. In the context of the larger study, it should be noted that, while our current study focused on women aged 50–74, we did provide services to women aged 40–49 and 75+ years. For these women, standard guidelines suggest the importance of shared decision making with one's primary care provider, as screening may not be cost effective and might be harmful for these age groups.

Conclusion

Despite these limitations, findings of this study offer important lessons for future research and practice, especially given the recent emphasis placed on patient navigators in the Patient Protection and Affordable Care Act.[31] First, our study is an important step forward in assessing the benefit of navigation by examining navigation longitudinally. Future randomized controlled trials are warranted to confirm our findings. Next steps further require more comprehensive detail regarding screening patterns, including assessment of adherence to evidence-based guidelines across a longer period of time. Second, this study relied more heavily on navigation administered by phone- and mail-based methods. These methods may be less costly than more traditional in-person navigation services. Future work should further compare and assess the relative effectiveness of different modes of delivery for long-term sustainable program planning and implementation.

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Author Disclosure Statement

No competing financial interests exist.

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