Predictors of resolution in navigated patients with abnormal cancer screening tests

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Background Patient navigation has been effective in improving cancer care, yet little is known about what predicts timely outcomes in navigated patients.

Objective We identified predictors of resolution of abnormal cancer screening tests in patients who received navigation.

Methods We examined data on patients with abnormal breast (n = 256) or cervical (n = 150) screening tests or symptoms who received navigation as part of the Ohio Patient Navigator Research Program during 2007-2010. We used multivariable Cox proportional hazards regression models to identify predictors of time to resolution (ie, when a patient's clinical abnormality or abnormal screening test was determined to be a benign condition or a cancer diagnosis).

Results The median time to resolution was 183 days for navigated patients with breast abnormalities and 172 days for navigated patients with cervical abnormalities. In patients with breast abnormalities, those who reported at least 1 barrier to care during navigation (HR, 0.66; 95% CI, 0.51-0.86) or higher perceived stress (HR, 0.90; 95% CI, 0.82-0.98) had slower resolution. Among patients with cervical abnormalities, those who reported at least 1 barrier to care during navigation had slower resolution (HR, 0.62; 95% CI, 0.42-0.91). Patients with cervical abnormalities had faster resolution if they had private health insurance, but this effect was present only in younger women (interaction $P = .003$).

Limitations Unknown generalizability of results because patients were female and from clinics in central Ohio.

Conclusions Several variables predicted whether patient navigation led to faster resolution, and predictors differed somewhat by disease site. Results will be useful in improving current patient navigation programs and designing future programs.

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Harold P Freeman introduced patient navigation (PN) in 1990 as a potential strategy for reducing health disparities in African Americans at a Harlem, New York, hospital.[1] PN has been described as a "barrier-focused intervention" that is provided to patients for a defined episode of cancer-related care; has a definite endpoint when the services provided are complete; targets defined health services that are required to complete an episode of cancer-related care; focuses on the identification of individual patient-level barriers to accessing cancer care; and aims to reduce delays in accessing the continuum of cancer care services.[2] Delays in cancer care have been associated with personal factors (eg, race, socioeconomic status, psychosocial constructs, and so on), interpersonal factors (eg, dissatisfaction with health care providers), and system factors (eg, appointment logistics).[3-6]

In recent decades, there has been a large number of cancer-related PN programs started in the United States. Many of the early programs tested the impact of PN on cancer screening behaviors or follow-up after the detection of a screening abnormality.[2,7] Several of those studies reported a positive effect of PN. More recently, the Patient Navigation Research Program (PNRP) was created and funded by the National Cancer Institute (NCI) and the American Cancer Society (ACS) to further examine the effectiveness of PN programs.[8] This cooperative effort involved PN studies that targeted vulnerable populations at 10 health care institutions across the United States. Most PNRP studies have shown that PN reduces the time from abnormal findings to diagnostic resolution in patients with breast, cervical, colorectal, and prostate abnormalities.[9-14] Diagnostic resolution occurred when a patient's clinical abnor-

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mality or abnormal screening test was determined to be a benign condition or a cancer diagnosis.

Despite a growing body of evidence that PN programs are effective in improving cancer-related care outcomes, little is known about what variables predict timely outcomes in navigated patients. Such information is critical for improving current PN programs and designing future programs. We examined data from the Ohio Patient Navigator Research Program (OPNRP) to identify predictors of diagnostic resolution in navigated patients.

Methods

Patient recruitment

The OPNRP has been described in detail elsewhere[13] and briefly here. The program had a primary goal of testing the Ohio ACS model of PN in reducing time to diagnostic resolution in patients with abnormal breast, cervical, or colorectal cancer screening tests or symptoms. It used a group-randomized trial design,[15] with medical clinics randomized to study condition (PN or comparison) and individual patients followed over time to determine the effect of the PN intervention. We randomized a total of 18 clinics to either PN or comparison, with clinics paired and randomized within pairs (resulting in 9 clinics in each condition).

We recruited patients at the participating clinics who met the following study eligibility criteria:

- At least 18 years old,
- A regular patient of the clinic (eg, not being seen only for a second opinion),
- Not cognitively impaired,
- Able to give informed consent,
- Identified as having either an abnormal cancer screening test, an abnormal diagnostic test, or an abnormal clinical finding leading to diagnostic testing for cervical, breast, or colorectal cancer,
- No history of cancer except for nonmelanoma cancer of the skin,
- Living outside a nursing home or institutional setting,
- No history of medical navigation, and
- Able to speak and understand English or Spanish.

Recruitment began with obtaining consent from potential patients' physicians. Once consent was obtained from the physician, a letter introducing the study was sent to the patient before any contact by the study staff. The study staff then called the patients to explain the study details and asked them if they would like to participate in the study. Recruitment occurred during 2007-2010. We obtained informed consent from all participants. The Ohio State University Institutional Review Board approved the study.

A total of 862 patients from the 18 clinics participated in the study.[13] We report data on 256 patients with a breast abnormality and 150 patients with a cervical abnormality from clinics who were randomized to receive PN, contacted by a navigator before resolution, and did not refuse navigation. We do not report data from comparison clinics because this paper focuses on predictors of resolution in navigated patients. We also do not report data on patients with colorectal abnormalities from clinics randomized to PN because of their small sample size (n = 27).

Intervention

Participating patients from PN clinics received the OPNRP intervention, which was guided by the Chronic Care Model,[16] social support theory,[17] and constructs of the Health Belief Model.[18] The OPNRP focused on removing barriers that exist for patients because of issues with communication and coordination of health care as patients navigate across different settings and among various providers. Patients from intervention clinics were assigned to 1 of 3 lay patient navigators. Navigators contacted patients by phone (or in person if no phone number was available). The navigator assessed patients' needs, facilitated interaction and communication with health care providers, connected patients to community and social support services, and provided health education and support.

Measures

The primary outcome was time to resolution of abnormalities (measured in number of days to resolution). (Diagnostic resolution occurred when a patient's clinical abnormality or abnormal screening test was determined to be a benign condition or a cancer diagnosis.) We obtained data from medical records to calculate time to resolution. Patients who did not resolve during the follow-up period were censored at 365 days.

Each patient completed a baseline questionnaire upon study enrollment and an end-of-study survey when their abnormality was resolved or the end of their follow-up period (ie, censored at 365 days). All patient-reported data for these analyses come from baseline surveys. Surveys used existing instruments to measure several psychosocial constructs, including the Perceived Stress Scale (PSS-14; possible range, 0-56),[19] Trust in Physician Scale (TPS; possible range, 11-55),[20] Perceived Social Support-Family (PSS-Fa; possible range, 0-20),[21] and Perceived Social Support-Friends (PSS-Fr; possible range, 0-20).[21] For the PSS-Fa and PSS-Fr, we classified patients as having low social support (scores ≤15) or high social support (scores ≥16). We used the Center for Epidemiologic Studies Depression (CES-D) scale to examine depression, with scores ≥16 suggestive of depressive symptoms.[22]

Patient navigators indicated the number and types of barriers to care, as reported by patients during their encounters. We classified patients as reporting no barriers or at least 1 barrier during the navigation process (ie, any barriers or no barriers). To further examine barriers for exploratory purposes, we also grouped barriers into 3main categories: patient-focused (eg, financial problems, comorbidities, et.); other-focused (eg, transportation issues, lack of child care, etc); and system-level barriers (eg, logistical issues with the health care system). Details about these barrier groups are provided elsewhere in the literature.[23] We also collected information on several demographic characteristics (Table 1).

Data analysis

We compared navigated participants with breast and cervical abnormalities using Fisher's exact test (categorical variables) and two-sample *t*-tests (continuous variables). Cox proportional hazards regression models were used to identify predictors of time to resolution among participants in PN arm of the study. Predictors significant at a 0.20 level in univariable models were included in a backwards selection process for constructing the multivariable model. Separate multivariable models were constructed for navigated participants with breast and cervical abnormalities, and we considered two-way interactions in both multivariable models. The multivariable models produced adjusted hazard ratios (HRs) and 95% confidence intervals (CIs). We evaluated the proportional hazards assumption of each predictor using diagnostic plots and examining the scaled Schoenfeld residuals,[24,25] with no violations of the assumption found. Analyses used Stata v10.1 (StataCorp, College Station, TX) and SAS v9.3 (SAS Institute, Cary, NC).

Results

Patient characteristics

Patients with breast abnormalities were older than were patients with cervical abnormalities (mean age, 52.9 years vs 35.7 years, respectively; $P < .001$). Patients with breast abnormalities were more likely than were patients with cervical abnormalities to be non-Hispanic white (74% vs 61%), married (60% vs 35%), have a college degree (54% vs 34%), report a household income of at least \$50,000 (65% vs 37%), and have private health insurance (72% vs 62%), all $P < .05$. Additional differences between patients with breast abnormalities and patients with cervical abnormalities are in Table 1.

TABLE 1 Characteristics of patients with abnormal breast (n = 256) or cervical screening tests or symptoms

Characteristic	Breast, n (%) (n = 256)	Cervix, n (%) (n = 150)	*P*
Mean age, y (SD)	52.9 (11.3)	35.7 (12.8)	<.001
Race			.007
White, non-Hispanic	190 (74)	92 (61)	
Other	66 (26)	58 (39)	
Marital status			<.001
Not married	102 (40)	97 (65)	
Married	154 (60)	53 (35)	
Education level			<.001
No college degree	118 (46)	99 (66)	
College degree	138 (54)	51 (34)	
Annual household income			<.001
<\$50,000	85 (35)	86 (63)	
≥\$50,000	155 (65)	51 (37)	
Health care coverage			.033
Public insurance /uninsured	71 (28)	55 (39)	
Private insurance	184 (72)	88 (62)	
Existing comorbidity			<.001
No	79 (31)	79 (54)	
Yes	175 (69)	67 (46)	
Barriers to care			.182
0	144 (56)	74 (49)	
≥1	112 (44)	76 (51)	
Patient-focused barrier			.154
0	179 (70)	94 (63)	
≥1	77 (30)	56 (37)	
Other-focused barrier			.090
0	235 (92)	129 (86)	
≥1 or more	21 (8)	21 (14)	
System-level barrier			.019
0	209 (82)	107 (71)	
≥1 or more	47 (18)	43 (29)	
Perceived stress, mean (SD)[a]	19.5 (7.6)	23.3 (8.8)	<.001
Trust in physician, mean (SD)[b]	45.4 (6.0)	43.8 (6.8)	.020
Depression			<.001
CES-D < 16	208 (82)	94 (63)	
CES-D ≥ 16	47 (18)	56 (37)	
Perceived Social Support-Family			.001
PSS-Fa < 16	53 (22)	53 (38)	
PSS-Fa ≥ 16	187 (78)	86 (62)	
Perceived Social Support-Friends			.035
PSS-Fr < 16	51 (21)	43 (32)	
PSS-Fr ≥ 16	188 (79)	93 (68)	

CES-D, Center for Epidemiologic Studies Depression; PSS-Fa, Perceived Social Support-Family; PSS-Fr, Perceived Social Support-Friends

[a]Measured with the Perceived Stress Scale (PSS-14). [b]Measured with the Trust in Physician Scale (TPS).

Note. Totals may be less than stated sample size because of missing data. Percentages may not sum to 100% because of rounding.

Resolution

Patients with breast abnormalities. The median time to resolution in navigated patients with a breast abnormality (n = 256) was 183 days. About 25% of those patients resolved within 63 days, with about 75% resolved by 224 days. In univariable analyses, patients who reported higher perceived stress or at least 1 barrier to care during navigation had slower resolution (both $P < .05$; Table 2). Additional variables included in the multivariable model-building process ($P < .20$) were age, perceived social support from friends, and trust in physician. In the final multivariable model, patients who reported higher perceived stress (HR, 0.90; 95% CI, 0.82-0.98) or at least 1 barrier to care during navigation (HR, 0.66; 95% CI, 0.51-0.86) had slower resolution. In exploratory analyses, we examined each barrier group in the multivariable model (replacing the any barriers vs no barriers variable) and found that patients who reported patient-focused barriers had slower resolution than did patients who did not report patient-focused barriers (HR, 0.53; 95% CI, 0.40-0.72). The presence of system-level barriers or other-focused barriers did not influence resolution.

Patients with cervical abnormalities. The median time to resolution in navigated patients with a cervical abnormality (n = 150) was 172 days. About 25% of those patients resolved within 88 days, with about 75% resolved by 261 days. In univariable analyses, patients who were older, had a college degree, had private health insurance, or reported higher trust in physician had faster resolution (all $P < .05$; Table 3). Patients who reported depressive symptoms, higher perceived stress, or at least 1 barrier to care during navigation had slower resolution (all $P < .05$). Additional variables included in the multivariable model-building process ($P < .20$) were household income, perceived social support from friends, and having a comorbidity.

In the final multivariable model, we found an interaction between age and whether or not patients had private health insurance (interaction $P = .003$). Patients with private health insurance had faster resolution at younger ages, with the difference dissipating as age increased (Figure 1). Multivariable results also suggested that patients who reported higher trust in their physician had faster resolution (5-unit increase HR, 1.15; 95% CI, 1.00-1.32, $P = .052$). Patients who reported at least one barrier to care during navigation had slower resolution (HR, 0.62; 95% CI, 0.42-0.91). In exploratory analyses, we examined each barrier group in the multivari-

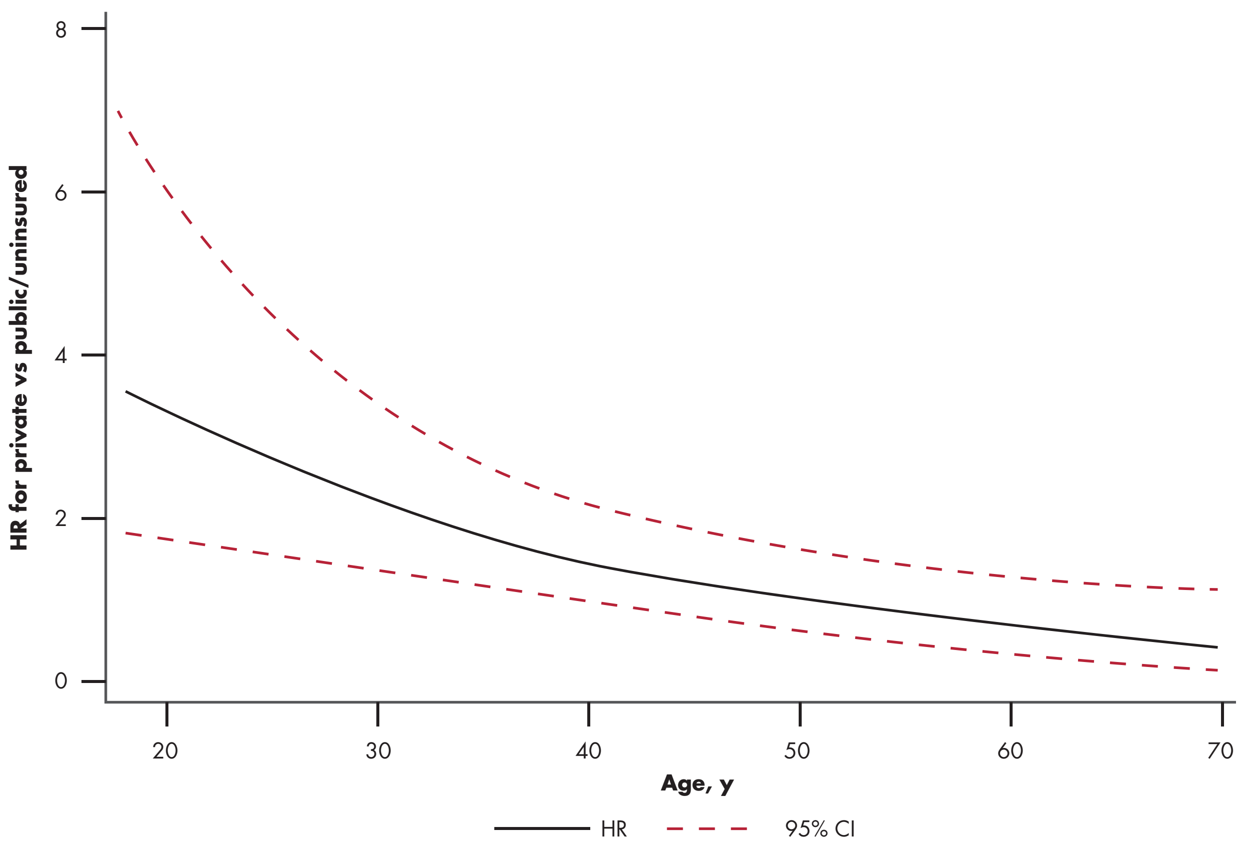

FIGURE 1 Model estimated hazard ratios showing the interaction between age and health care coverage (private health insurance vs nonprivate health insurance [ie, public health insurance or uninsured]) on the resolution of abnormal cervical screening tests.

able model (replacing the any barriers vs no barriers variable) and found that patients who reported other-focused barriers had a slower rate of resolution than did patients who did not report other-focused barriers (HR, 0.52; 95% CI, 0.28-0.94). The presence of patient-focused or system-level barriers did not have an impact on resolution.

Discussion

We analyzed data collected on patients from the OPNRP to identify variables that predict timely outcomes in navigated patients. Slower time to diagnostic resolution was documented in patients with breast or cervical abnormalities who reported at least 1 barrier to care during navigation. These findings are consistent with past research in nonnavigated patients that also found barriers to care delayed receipt of cancer care.[3,4] Resolution in patients with breast abnormalities was affected by patient-focused barriers, whereas resolution in patients with cervical abnormalities was affected by other-focused barriers. That patient-focused barriers to care (which included comorbidities and fear[23]) affected diagnostic resolution in patients with breast abnormalities was not surprising because those patients were more likely to have comorbidities and fear is a common finding in patients with abnormal breast tests or clinical findings.[3,26] In patients with cervical abnormalities, it is likely that other-focused barriers affected resolution because that barrier grouping included issues related to employment and child care. Those issues are likely more problematic for younger patient populations, such as the patients with cervical abnormalities in this study. Future PN programs should consider how different barriers may affect resolution according to disease site.

Patients with cervical abnormalities had faster resolution if they had private health insurance compared with those with public or no health insurance, which is consistent with previous studies.[5] However, the effect of private health insurance was present only in younger women, with the difference dissipating as age increased. That pattern is likely because most younger adults without private health insurance being uninsured, whereas many older adults without private health insurance have public health insurance (eg, Medicare).[27] We were not able to separate out women with public insurance from

TABLE 2 Predictors of time to resolution in patients with abnormal breast screening tests (n = 256)

Predictor	Hazard ratio (95% CI) Univariable	Multivariable
Age (5-year increase)	1.05 (0.99-1.11)	–
Race		
White, non-Hispanic	1.19 (0.88-1.61)	–
Other	ref.	–
Marital status		
Not married	ref.	–
Married	1.09 (0.84-1.41)	–
Education level		
No college degree	ref.	–
College degree	0.98 (0.76-1.26)	–
Household income		–
<$50,000	ref.	–
≥$50,000	0.97 (0.74-1.28)	–
Healthcare coverage		–
Public insurance /uninsured	ref.	–
Private insurance	1.05 (0.79-1.39)	–
Existing comorbidity		–
No	ref.	–
Yes	0.87 (0.66-1.14)	–
Barriers to care		–
0	ref.	ref.
≥1	0.64 (0.50-0.84)*	0.66 (0.51-0.86)*
Perceived stress[a] (5-unit increase)	0.89 (0.81-0.97)*	0.90 (0.82-0.98)*
Trust in physician[b] (5-unit increase)	1.09 (0.98-1.22)	–
Depression		–
CES-D < 16	ref.	–
CES-D ≥ 16	0.85 (0.61-1.19)	–
Perceived Social Support-Family		–
PSS-Fa < 16	ref.	–
PSS-Fa ≥ 16	1.17 (0.86-1.60)	–
Perceived Social Support-Friends		–
PSS-Fr < 16	ref.	–
PSS-Fr ≥ 16	1.35 (0.98-1.86)	–

CES-D, Center for Epidemiologic Studies Depression; CI, confidence interval; HR, hazard ratio; PSS-Fa, Perceived Social Support-Family; PSS-Fr, Perceived Social Support-Friends; ref, referent group

[a]Measured with the Perceived Stress Scale (PSS-14). [b]Measured with the Trust in Physician Scale (TPS).

*$P < .05$

Note. The multivariable model included 255 patients because of missing data for potential predictors. Dashes (–) indicate that variable was not included in multivariable model following a backwards selection process.

TABLE 3 Predictors of time to resolution in patients with abnormal cervical screening tests (n = 150)

Predictor	Hazard ratio (95% CI) Univariable	Multivariable
Age (5-year increase)	1.09 (1.02-1.17)*	See below interaction with health care coverage
Interaction: Age-Public insurance/uninsured	na	1.18 (1.07-1.31)[†]
Interaction: Age-Private insurance	na	0.97 (0.89-1.06)
Race		
White, non-Hispanic	1.02 (0.72-1.45)	–
Other	ref.	–
Marital status		
Not married	ref.	–
Married	1.19 (0.84-1.70)	–
Education level		
No college degree	ref.	–
College degree	1.65 (1.15-2.36)*	–
Household income		
<$50,000	ref.	–
≥$50,000	1.41 (0.98-2.02)	–
Health care coverage		
Public insurance/uninsured	ref.	
Private insurance	1.97 (1.35-2.88)**	See above interaction with age
Existing comorbidity		
No	ref.	–
Yes	0.72 (0.51-1.03)	–
Barriers to care		
0	ref.	ref.
≥1	0.51 (0.35-0.73)**	0.62 (0.42–0.91)*
Perceived stress[a] (5-unit increase)	0.87 (0.78-0.97)*	
Trust in physician[b] (5-unit increase)	1.15 (1.00-1.33)*	1.15 (1.00–1.32)
Depression		
CES-D < 16	ref.	–
CES-D ≥ 16	0.65 (0.45-0.94)*	–
Perceived Social Support-Family		
PSS-Fa < 16	ref.	–
PSS-Fa ≥ 16	1.20 (0.83-1.74)	–
Perceived Social Support-Friends		
PSS-Fr < 16	ref.	–
PSS-Fr ≥ 16	1.41 (0.95-2.08)	–

CES-D, Center for Epidemiologic Studies Depression; CI, confidence interval; HR, hazard ratio; na, not applicable; PSS-Fa, Perceived Social Support-Family; PSS-Fr, Perceived Social Support-Friends

[a]Measured with the Perceived Stress Scale (PSS-14). [b]Measured with the Trust in Physician Scale (TPS).

[†]*P* = .003 for interaction **P* < .05 ***P* < .001

Note. The multivariable model included 143 patients because of missing data for potential predictors. Dashes (–) indicate that variable was not included in multivariable model following a backwards selection process.

those with no insurance in our analyses because of the small number of uninsured women. We believe our results still provide early insight into the effects of private health insurance on resolution in women with cervical abnormalities and how that effect may vary with age. PN programs need to be aware that younger women with cervical abnormalities who do not have private health insurance particularly struggle to reach timely resolution.

A few of the psychosocial variables examined were predictive of resolution. Patients with breast abnormalities who reported higher perceived stress had slower resolution, whereas results also suggested that patients with cervical abnormalities who reported higher trust in their physician had faster resolution. These constructs have been correlated with health outcomes in previous research. Patients' relationships with their physicians has affected adherence to medical management[28] and receipt of cancer care,[3,4] and higher levels of perceived stress have been associated with increased risk of all-cause mortality and myocardial infarction.[29,30] Our results lend further support to the potentially important role of these variables in affecting health outcomes and suggest they may be important modifiable targets for improving the effectiveness of future PN programs.

Study strengths include a demographically diverse patient population recruited from several clinics and using data from medical records to determine time to resolution. Limitations include unknown generalizability of results because all of the patients included in these analyses were female and recruited from clinics in central Ohio. We were not able to include patients with colorectal abnormalities in analyses because of the small sample size, and predictors of resolution may differ for PN programs structured differently than the OPNRP (eg, those that use clinic-based navigators).

Several variables predicted whether PN led to faster diagnostic resolution in patients with screening abnormalities. Reducing barriers to care is an important strategy for reducing time to resolution in patients with breast or cervical abnormalities. Additional targets for reducing time to resolution may differ by disease site. The results of this study will be useful in improving current PN programs and designing future programs.

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