

Feasibility of Patient Navigation to Improve Breast Cancer Care in Malaysia

abstract

Purpose Late stage at presentation and poor adherence to treatment remain major contributors to poor survival in low- and middle-income countries (LMICs). Patient navigation (PN) programs in the United States have led to improvement in diagnostic or treatment timeliness, particularly for women in lower socioeconomic classes or minority groups. To date, studies of PN in Asia have been limited. We aimed to assess the feasibility of PN in a state-run hospital in an LMIC and to report the impact on diagnostic and treatment timeliness for patients in its first year of implementation.

Methods We established PN in a dedicated breast clinic of a Malaysian state-run hospital. We compared diagnostic and treatment timeliness between navigated patients (n = 135) and patients diagnosed in the prior year (n = 148), and described factors associated with timeliness.

Results Women with PN received timely mammography compared with patients in the prior year (96.4% v 74.4%; $P < .001$), biopsy (92.5% v 76.1%; $P = .003$), and communication of news (80.0% v 58.5%; $P < .001$). PN reduced treatment default rates (4.4% v 11.5%; $P = .048$). Among navigated patients, late stage at presentation was independently associated with having emotional and language barriers ($P = .01$). Finally, the main reason reported for delay, default, or refusal of treatment was the preference for alternative therapy.

Conclusion PN is feasible for addressing barriers to cancer care when integrated with a state-run breast clinic of an LMIC. Its implementation resulted in improved diagnostic timeliness and reduced treatment default. Wider adoption of PN could be a key element of cancer control in LMICs.

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INTRODUCTION

Breast cancer is a major public health burden in Asia. In Malaysia, the age-standardized incidence rate is 38.7 per 100,000 women per year, and the number of patients with breast cancer are projected to continue increasing.¹ Notably, Malaysian patients with breast cancer have one of the lowest survival rates in the Asia-Pacific region, with a 5-year survival of only 49%,^{1,2} compared with up to 90% in the United States.³

A major reason for poor survival among Malaysian women is late presentation (43% of breast cancers present at stages III and IV).⁴ Past research in Malaysia has shown that patients with breast cancer attending subsidized services at public hospitals have higher mortality compared with patients attending private hospitals (hazard ratio, 1.59; 95% CI, 1.36 to 1.85),⁵ and this is likely driven by differences in patient socioeconomic status. Women of lower socioeconomic status have more high-risk health behaviors, poorer nutritional status, and poorer health literacy, and are less likely to receive screening

and treatment.⁶ Taken together, this suggests that focusing on achieving timely diagnosis and treatment completion, particularly among lower income groups, is a key priority in improving breast cancer survivorship in the region.

Patient navigation (PN) is a patient-centered approach to improving health care delivery by promoting timely movement of a patient through a complex health care continuum.⁷ PN serves to improve coordination of the health care system and, on an individual level, helps patients overcome barriers to cancer care. A systematic review in 2016 showed that PN improved diagnostic timeliness and helped women receive proper treatment for breast cancer.⁸ Some studies showed improved diagnostic timeliness only in a subgroup of women, namely, older women,⁹ Asian or Hispanic women paired with an Asian or Hispanic navigator,¹⁰ or women who were most likely to experience delays in diagnostic resolution.¹¹ PN also improved overall adherence to quality care indicators¹² and decreased cancer-related distress.¹³ By addressing barriers

to cancer care, PN could improve breast cancer survival in LMICs, particularly among women in lower socioeconomic groups.

PN could be an effective approach to improving breast cancer care in Asia, but its implementation in the different cultural and resource settings in the region is not well studied. Case studies in Singapore, Nepal, and India have highlighted the challenges of executing PN, including difficulties in coordinating care and inefficiencies in patient flow, and pointed to factors that delay care, such as financial constraints and low health literacy.¹⁴⁻¹⁶ However, no study has determined the impact of PN on patient outcomes in Asia.

We integrated PN in a breast clinic, the Pink Ribbon Centre (PRC), in a suburban state-run secondary referral hospital (Hospital Tengku Ampuan Rahimah, Klang, Malaysia). In this article, we report the feasibility of PN in this state-run hospital in an LMIC. We also assessed whether PN improved diagnostic and treatment timeliness for patients in its first year of implementation, compared with patients with breast cancer diagnosed in the previous year.

METHODS

Patients With Breast Cancer

From November 2014 to December 2015, 225 women were referred to the PRC from the hospitals' surgical outpatient clinics. All patients diagnosed with breast cancer (N = 146) were recruited to the PN program. The study was approved by the Malaysian Research Ethics Committee (NMRR-17-2951-35223), and permission to use patient data was sought from the hospital under the governance of the Malaysian Ministry of Health.

Patient Navigation

We trained three qualified nurses in general nursing, oncology, and breast care and surgery as nurse navigators in the PRC. Navigators aimed to improve diagnostic and treatment timeliness, reduce default rates, and increase treatment completion rates. To achieve these aims, navigators were trained to provide patient and family education, supportive care and visits, and practical help in overcoming individual patient barriers. A community navigator addressed patients' social welfare needs that hinder completion of cancer care.

In addition, the PRC had an assigned surgical medical officer, increased clinic days, dedicated phone lines, and implemented e-tracking and appointment reminder calls. There were service-level agreements with the radiology and pathology departments for increased service allocations. Patients with early-stage breast cancer received a culturally relevant decision aid tool to enhance shared decision making.

Data Collection

At the first PRC visit, navigators administered a baseline questionnaire to collect patient data and identify potential barriers to cancer care. The navigators' workload was recorded at the end of every week. Using an e-tracking system, we collated patient milestones, which were used to determine referral timeliness (time from referral to first visit at the PRC), diagnostic timeliness (time from the first visit to the communication of diagnosis), and treatment initiation timeliness (time from diagnosis to surgery or the initiation of neoadjuvant treatment, whichever was first). Defaulters were defined as patients with breast cancer who were lost to follow-up before treatment initiation and were not contactable or refused contact with the PRC. Data for patients from the year before the PN program began were obtained. In addition, the surgical medical officer collected information on cancer stage, treatment received, and reasons for treatment delays, if available.

Statistical Analysis

Standard descriptive statistics were used to describe the cohort. We assessed the effect of PN on diagnostic and treatment timeliness, using state-defined key performance indicators,¹⁷ by comparing the navigated cohort with patients with breast cancer from the preceding year. Factors associated with cancer stage were assessed using Wilcoxon rank sum tests for continuous data and Fisher's exact test for categorical data. Multivariable logistic regression was used to determine the independent predictors of late stage at presentation. All analyses were two-sided, and *P* values < .05 were considered statistically significant. All statistical tests were performed using the R statistical environment version 3.4.0. Patient notes were transcribed and analyzed for the subset of women who had delayed, refused, or defaulted on primary treatment.

RESULTS

Cohort

We describe here the feasibility and performance of PN for patients with breast cancer in a Malaysian suburban state-run hospital. From November 2014 to December 2015, 225 women were referred to the PRC from the surgical outpatient department. All women diagnosed with breast cancer (N = 146) were included in the analysis, excluding women who received surgical treatment (n = 8) or who died (n = 3) before visiting PRC. We report the outcomes for these 135 women up to completion of treatment, treatment default, death, or to December 31, 2016. The care pathway is described in Appendix [Figure A1](#).

The baseline demographic characteristics of the 135 patients with breast cancer diagnosed in the first year are listed in [Table 1](#). The median age was 53.0 years (interquartile range, 46.5 to 62.0 years). Half of patients (50.4%) were ethnically Malay, 28.1% were Indian, and 19.3% were Chinese. Most patients (61.5%) did not complete secondary education. The median monthly household income was US \$467 (interquartile range, \$234 to \$701). More than one in six women (17.8%) lived below the national poverty line (\leq US \$187/month). Nearly half (48.9%) were diagnosed with late-stage disease (stage III or IV).

The barriers to cancer care that were identified by navigators and reported by patients are listed in [Table 2](#). The most common barrier was poor breast health literacy (97.0%). We found that half of the patients (61.5%) could not name a sign of breast cancer, 74.8% could not name a risk factor, 68.1% did not know about available screening services, and 74.8% did not know the recommended age to start screening. Other barriers identified by the navigators included logistic (38.5%), financial (38.5%), emotional (35.6%), and communication barriers (23.7%).

Women presenting with late-stage breast cancer were more likely to have emotional barriers (45.5% v 26.1%; $P = .021$), preferred to speak or read in languages other than English (19.7% v 36.2%; $P = .036$; and 16.7% v 31.9%; $P = .045$, respectively), had lower monthly household incomes (US \$350 v \$540; $P = .023$), were interdepartmental referrals (31.8% v 14.5%; $P = .044$), and were less likely to have their own transport (36.4% v 56.5%; $P = .048$; [Table 3](#)). Our model using multivariable logistic regression (Appendix [Table A1](#)) showed that late stage at

presentation was independently associated with having emotional and language barriers.

Operations

We listed the navigators' workload for the year in [Table 4](#). Nearly half of the patients (40.0%) received referrals for social welfare support. More than one in six patients (17.0%) received community navigation, including support for transportation, financial aid, food, and legal assistance.

Impact of PN

We assessed diagnostic and treatment timeliness with PN ([Table 5](#)). There were significant improvements with PN compared with the year before in timeliness for mammogram (0 v 1 day; $P < .001$), timeliness of biopsy (0 v 1 day; $P < .001$), and communication of news (11 v 13 days; $P = .001$). Time to surgery decreased from 27.0 to 22.0 days ($P = .121$) with PN, but time to neoadjuvant therapy increased from 25.0 to 38.0 days ($P = .133$).

In [Table 6](#), the proportion of women meeting state-defined key performance indicators on diagnostic and treatment timeliness were significantly improved for mammography (96.4% v 74.4%; $P < .001$), biopsy (92.5% v 76.1%; $P = .003$), and communication of news (80.0% v 58.5%; $P < .001$) with PN. The proportion of patients who defaulted before treatment decreased significantly, from 11.5% to 4.4% with PN ($P = .048$).

Factors Associated With Delay, Refusal, or Default of Primary Treatment

For 14 of the 50 patients who delayed, refused, or defaulted on primary treatment, qualitative analysis of patient notes highlighted four themes: belief in alternative therapy (n = 9), fear of treatment adverse effects (n = 2), family influence on health care decision (n = 2), and delaying treatment for a life or social event (n = 2). We observed that many women delayed or refused medical treatment in favor of alternative therapy, including local traditional medicine, Chinese medicine, and nutritional supplements.

DISCUSSION

We show that PN improves diagnostic and treatment metrics for patients and is feasible in a

Table 1. Baseline Demographic Characteristics of Patients (n = 135)

Variable	Median (IQR)	Frequency	%
Age (years)	53.0 (46.5-62.0)		
< 40		16	11.9
40-49		35	25.9
50-59		44	32.6
> 60		40	29.6
Ethnicity			
Malay		68	50.4
Indian		38	28.1
Chinese		26	19.3
Foreigner		3	2.2
Religion			
Muslim		78	57.8
Hindu		27	20.0
Buddhist		24	17.8
Others		4	2.9
Highest education level attained			
No schooling		17	12.6
Primary schooling		37	27.4
Lower secondary schooling (forms 1-3)		29	21.5
Upper secondary schooling (forms 4-6)		39	28.9
Certificate, diploma, college, or degree		13	9.7
Monthly household income (US \$)	470 (230-700*)		
≤ RM800 (< 180)		24	17.8
RM800-1,500 (180-350)		26	19.3
RM1,500-3,000 (350-690)		49	36.3
> RM3,000 (> 690)		32	23.7
Employment			
Not employed		49	36.3
Employed		86	63.7
Marital status			
Married and still partnered		72	53.3
Single		34	25.2
Widowed		20	14.8
Divorced		6	4.4
Stage at diagnosis			
0		5	3.7
I		15	11.1
II		49	36.3
III		40	29.6
IV		26	19.3

Abbreviations: IQR, interquartile range; RM, Malaysian ringget; US \$, US dollars.

*RM converted to US \$ using RM1 = US \$0.23, rounded to the nearest \$10.

Table 2. Potential Barriers to Cancer Care (n = 135)

Barriers Identified by Navigators	Patient-Reported Information	Frequency	%
Knowledge of breast cancer		131	97.0
	Don't know any signs of breast cancer	83	61.5
	Don't know any risk factors for breast cancer	101	74.8
	Don't know about breast cancer screening availability in Malaysia	92	68.1
	Don't know about the right screening age	101	74.8
Communication		32	23.7
	Prefers to speak in languages other than English	95	70.4
	Prefers to read in languages other than English	99	73.3
Logistic		52	38.5
	Distance from hospital \geq 15 km	44	32.6
	Transportation		
	Public	13	9.6
	Family or friend	58	43.0
Financial	Own vehicle	63	46.7
		52	38.5
	Have dependents \leq 17 years old	48	35.6
Emotional		48	35.6
	Living alone	7	5.2
	No support from others	5	3.7
	Bad experience with health care	14	10.4
	Previous life crisis*	62	45.9
Others		27	20.0
	Family issues†	8	5.9
	Work issues‡	5	3.7
	Belief in alternative medicine	5	3.7
	Comorbidities	65	48.1
	Health care decisions		
	Jointly made	48	35.6
	Made by her husband or family	49	36.3
Own	37	27.4	

*Life crisis included abuse, divorce, or death of a child or husband.

†Family issues included strained family dynamics, having dependents with psychiatric issues, having elderly parents, or being a single parent of a young child.

‡Work issues included heavy responsibility at work, new job, or poor employer support.

dedicated breast clinic of a hospital in an LMIC. To our knowledge, this is the first PN report on quantitative outcomes in an LMIC. This study shows the success of PN in improving timely diagnosis, reducing treatment default, and achieving state-defined key performance indicators.

The ability of PN to improve diagnostic resolution is supported by strong evidence in the United States.⁸ The beneficial effect of PN was greatest among patients with the most challenges in diagnostic resolution, such as in at-risk populations that faced greater financial, health care, and social service barriers.^{18,19} Furthermore, a

ceiling effect was observed where PN had little or no impact when the baseline diagnostic resolution rates were 90% or greater.¹⁴ Collectively, this indicates that PN programs can be used to improve diagnostic resolution rates and timeliness for patients with breast cancer facing specific barriers to cancer care.

Consistent with previous literature, we did not observe improvements in treatment timeliness with PN.²⁰ A systematic review examined seven studies from 1990 to 2015 that investigated improvements in breast cancer treatment initiation with PN.²⁰ The majority of studies (five of

Table 3. Factors Associated With Late-Stage Breast Cancer

Factors	Stage at Diagnosis				P
	Early, No.*	%	Late, No.	%	
No. of patients	69	51.1	66	48.9	
Referral					.044
Primary care	42	60.9	33	50.0	
Interdepartmental	10	14.5	21	31.8	
Other government hospitals	16	23.2	10	15.2	
Private hospitals	0	0	1	1.5	
Ethnicity					.649
Malay	32	46.4	36	54.5	
Indian	22	31.9	16	24.2	
Chinese	14	20.3	12	18.2	
Barriers identified by navigators					
Knowledge of breast cancer	67	97.1	64	97.0	.999
Don't know any signs of breast cancer	42	60.9	41	62.1	.999
Don't know any risk factors for breast cancer	48	69.6	53	80.3	.169
Don't know about breast cancer screening availability in Malaysia	48	69.6	44	66.7	.854
Don't know the right screening age	54	78.3	47	71.2	.456
Communication	12	17.4	20	30.3	.105
Prefers to speak in languages other than English	43	62.3	52	78.8	.036
Prefers to read in languages other than English	45	65.2	54	81.8	.045
Don't read English or Malay	14	20.3	17	25.8	.541
Logistics	22	31.9	30	45.5	.115
Median distance from hospital in km (IQR)	10.4	(5.2-18.7)	9.0	(5.7-18.2)	.982
Transportation					.048
Public	6	8.7	7	10.6	
Family or friend	23	33.3	35	53.0	
Own vehicle	39	56.5	24	36.4	
Financial	21	30.4	31	47.0	.054
Have dependents \leq 17 years old	26	37.7	22	33.3	.719
Not employed	42	60.9	42	63.6	.858
Median monthly household income, US \$ (IQR)†	540	(260-690)	350	(200-690)	.023
Emotional	18	26.1	30	45.5	.021
Living alone	3	4.3	4	6.1	.718
No support from others	2	2.9	3	4.5	.676
Bad experience with health care	7	10.1	7	10.6	.999
Previous life crisis	32	46.4	30	45.5	.862
Other patient-reported information					
Health care decisions					.210
Jointly made	24	41.4	24	48.0	
Made by their husband or family	21	36.2	28	56.0	
Own	23	39.7	14	28.0	
Education					.393
No schooling	9	13.0	8	12.1	
Schooling up to lower secondary level	30	43.5	36	54.5	

(Continued on following page)

Table 3. Factors Associated With Late-Stage Breast Cancer (Continued)

Factors	Stage at Diagnosis				P
	Early, No.*	%	Late, No.	%	
Upper secondary and more	30	43.5	22	33.3	
Married and still partnered	35	50.7	37	56.0	.489
Comorbidities	38	55.1	27	40.9	.122

NOTE. Bold type indicates $P < .05$.

Abbreviation: IQR, interquartile range; US \$, US dollars.

*Early breast cancer includes stage 0, I, and II.

†Malaysian ringget converted to US \$ using Malaysian ringget 1 = US \$0.23, rounded to the nearest \$10.

seven) did not show any statistically significant impact.²⁰ The two studies that showed a significant impact were PN programs in a medically underserved population in the United States, such as women in extreme poverty and in geographically isolated areas.²⁰ Malaysia uses a universal health care system that subsidizes services to all citizens, making health care affordable and accessible for most of the population. It is possible that, in our study population, the cost of treatment is not the main barrier to treatment initiation.

We propose that the reduction in treatment default rates was the main benefit of PN in our

population. Consistent with our finding, PN has also been shown to significantly reduce no-show rates for colposcopy after an abnormal cervical smear (49.7% v 29.5% with PN, $P < .001$).²¹ Patient default is associated with the lack of psychological support, logistic or physical difficulty in accessing health care, and patient preference for female doctors.²²⁻²⁴ These barriers can be actively overcome with PN.

Belief in alternative therapy was the most common reason to delay, default on, or refuse treatment.²⁵ In Malaysia, patients with breast cancer are often offered unsolicited advice and sometimes coerced into using alternative medicine

Table 4. Navigator Workload

Navigator Work	Total No.
Patients, No. (%)	135 (100.0)
Patients who received social service referrals, No. (%)	54 (40.0)
Patients who received community navigation, No. (%)	23 (17.0)
No. of partnered community organizations	8
Reminder calls	1,204
Home visits	5
General counseling sessions	65
Preprocedure counseling sessions	
Preanesthesia	69
Preoperation	78
Prechemotherapy	50
Preradiotherapy	38
Prehormonal therapy	11
Postprocedure reinforcements	
Postoperation education sessions	36
Postmastectomy breast prosthesis referrals	51
Treatment of adverse effects counseling sessions	38
Supportive ward visits	
Preoperation	69
Postoperation	69
First chemotherapy session	27
Subsequent chemotherapy sessions	130

Table 5. Diagnostic and Treatment Timeliness With Patient Navigation

Treatment Stages	Year Before PN (n=148)			Year With PN (n=135)			P
	No.	Median days	IQR	No.	Median No. of Days	IQR	
Time from receipt of referral to patient's first visit to the PRC		n/a		135	2.0	0-5.0	
Time from first visit to							
Mammogram	125*	1.0	0-8.0	83*	0	0-1.0	< .001
Biopsy	138*	1.0	0-7.0	93*	0	0-1.0	< .001
Communication of news	142*	13.0	8.0-17.8	125*	11.0	5.0-14.0	.001
Family counseling		n/a		91*	3.0	0-7.0	
Time from diagnosis† to							
Surgery‡	80	27.0	16.0-40.3	72	22.0	13.8-34.3	.121
Neoadjuvant therapy	16	25.0	14.8-39.0	26	38.0	21.0-164.8	.133

NOTE. Bold type indicates $P < .05$.

Abbreviations: IQR, interquartile range; n/a, information that was not collected for the year before PN; PN, patient navigation; PRC, Pink Ribbon Centre.

*Excludes patients who received the service (eg, mammogram, biopsy, or communication of news) before first visit.

†Date of diagnosis is date of communication of news or date of first visit if communication of news is before first visit.

‡Definitive surgery is any surgical procedure that results in the removal of a tumor, including diagnostic surgical procedures.

by family and friends.^{26,27} The other reasons for seeking alternative therapy include the belief that modern treatment offers poor life quality and the need for emotional support in the face of denial.²⁶ Through our experience, nurse navigators can play a crucial role in alleviating these barriers by acknowledging cultural beliefs, providing emotional support and consistent communication, and improving health literacy,

thereby empowering women to make informed decisions about their treatment.

We observed that some women presented to the emergency, medical, or orthopedics departments before arrival at the PRC. These women were more likely to be unaware of or were in denial about their breast cancer and therefore were more likely to present in crisis mode and at later stages. This highlights the need for better

Table 6. State-Defined Key Performance Indicators With Patient Navigation

Key Performance Indicators	Year Before PN (n = 148)			Year With PN (n = 135)			P
	No.	No. of Patients Meeting the Definition	%	No.	No. of Patients Meeting the Definition	%	
Referral timeliness*		n/a		135	127	94.1	
Diagnostic timeliness†							
Mammogram ≤ 7 days	125‡	93	74.4	83‡	80	96.4	< 0.001
Biopsy ≤ 7 days	138‡	105	76.1	93‡	86	92.5	0.003
Communication of news ≤ 14 days	142‡	83	58.5	125‡	100	80.0	< 0.001
Treatment initiation timeliness§							
Surgery ≤ 4 weeks	80	44	55.0	72/72	47	55.0	0.261
Neoadjuvant therapy ≤ 4 weeks	16	9	56.3	26	11	42.3	0.575
Defaulters		17	11.5		6	4.4	0.048

NOTE. Bold type indicates $P < .05$.

Abbreviations: n/a, information that was not collected for the year before PN; PN, patient navigation.

*Time from first visit to the Pink Ribbon Centre.

†Excludes patients who received the service (eg, mammogram, biopsy, or communication of news) before first visit.

‡Time from receipt of referral to patient's first visit to the Pink Ribbon Centre.

§Time from the date of diagnosis (date of communication of news or date of first visit if communication of news occurred elsewhere).

||No. of defaulters over total No. of patients with breast cancer registered during the respective year.

general awareness of the signs and symptoms of breast cancer and improved health literacy in the community. Therefore, to improve survival from breast cancer, there is an urgent need to address the issue of late presentation, such as by expanding PN to include innovative community interventions that address population-specific and/or culture-specific barriers.

Although ours was a prospective study, it may be subject to bias because we used a historical comparison without full follow-up data. Furthermore, half of the navigated women were unable to use the culturally relevant decision aid tool in the decision-making process, which was designed for patients with early-stage breast cancer. However, to our knowledge, this is the first quantitative study of PN in an LMIC.

Importantly, this PN program ensured cultural acceptability by employing multilingual, trained hospital nurses as navigators. Our findings suggest that PN, if implemented nationally and tailored for cultural sensitivity, may improve outcomes for patients with breast cancer in Malaysia. PN integrated into a breast clinic in a Malaysian state-run hospital is feasible and successful in improving diagnostic timeliness and reducing treatment default, but its effect on timely treatment initiation, treatment adherence, and survival requires additional investigation.

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Appendix

Fig A1. Patient flow and timeline in the patient navigation (PN) program. (*) Patients who died before the first visit (n = 3), received surgical treatment before arriving at Pink Ribbon Centre (PRC; n = 8). (†) Transferred to other hospitals (n = 17), unsuitable for primary treatment (n = 8), defaulted treatment (n = 6), refused treatment (n = 4), and died before treatment initiation (n = 2).

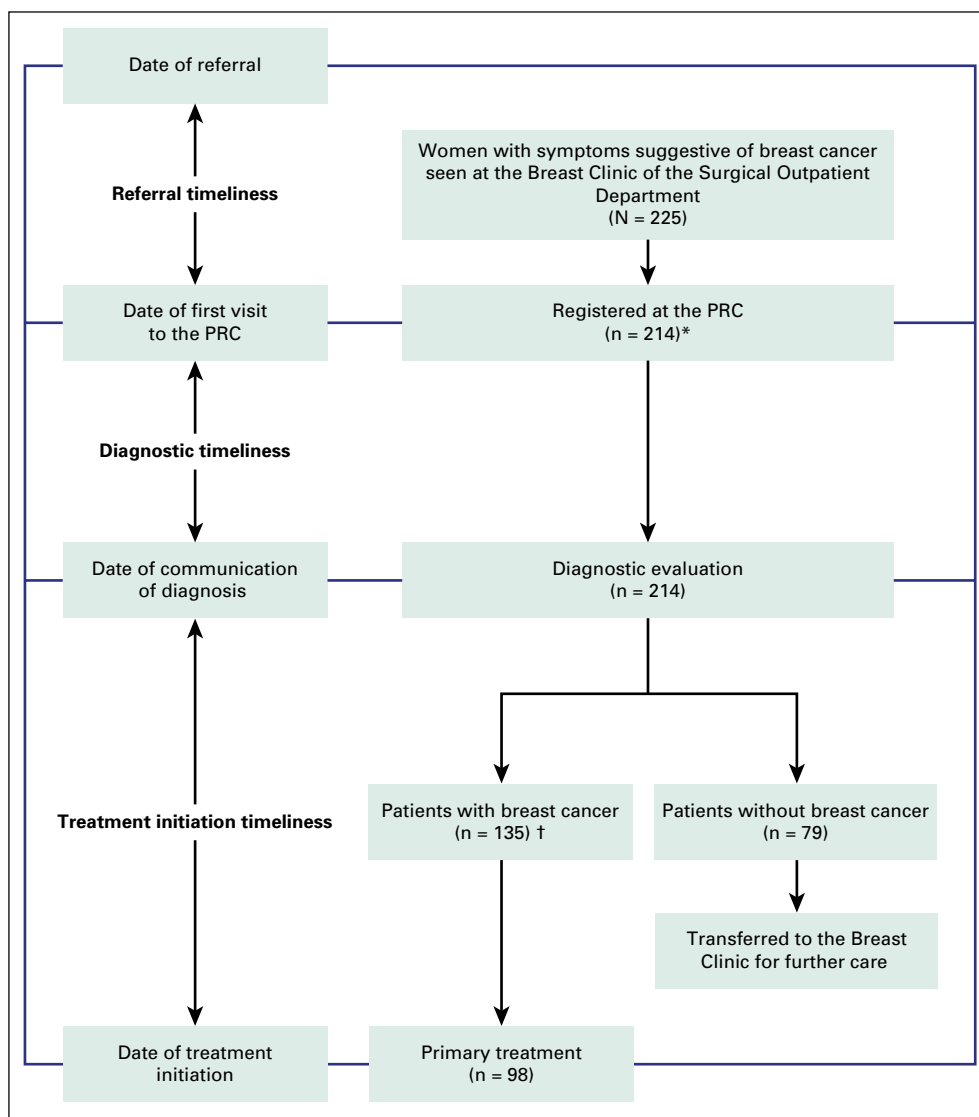


Table A1. Multivariable Analysis of Factors Associated With Late Stage at Presentation

Variable	Unadjusted			Adjusted		
	β	95% CI	P	β	95% CI	P
Navigator identified emotional barrier	.95	0.23 to 1.69	.01	1.22	0.38 to 2.12	.01
Monthly household income	.00	0.00 to 0.00	.04	0.00	0.00 to 0.00	0.21
Prefers to speak in languages other than English	.89	0.12 to 1.69	.03	1.16	0.26 to 2.14	.01
Referred						
From primary care	Ref					
Interdepartmental	.98	0.12 to 1.90	.03	1.24	0.25 to 2.31	.02
From other government hospitals	-0.07	-0.99 to 0.83	.88	-0.30	-1.37 to 0.73	.58
Transportation						
Family or friend	Ref					
Public transportation	0.05	-1.17 to 1.35	.94	-0.19	-1.45 to 0.31	.80
Own vehicle	-0.91	-1.65 to -0.18	.02	-0.57	-1.71 to 1.32	.20

NOTE. Bold type indicates $P < .05$

Abbreviation: Ref, reference.