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Patient Navigation Improves Cancer Diagnostic Resolution: An Individually Randomized Clinical Trial in an Underserved Population

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Abstract

Background—Barriers to timely resolution of abnormal cancer screening tests add to cancer health disparities among low income, uninsured and minority populations. We conducted a randomized trial to evaluate the impact of lay patient navigators on time to resolution and completion of follow-up testing among patients with abnormal screening tests in a medically underserved patient population.

Methods—Denver Health (DH), the safety-net healthcare system serving Denver, is one of ten performance sites participating in the Patient Navigation Research Program (PNRP). Of 993 eligible subjects with abnormal screening tests randomized to navigation and no-navigation (control) arms and analyzed, 628 had abnormal breast screens (66 abnormal clinical breast examinations, 304 BIRADS 0, 200 BIRADS 3, 58 BIRADS 4 or 5) while 235 had abnormal colorectal and 130 had abnormal prostate screens.

Results—Time to resolution was significantly shorter in the navigated group (stratified log rank test, $p<0.001$). Patient navigation improved diagnostic resolution for patients presenting with mammographic BIRADS 3 ($p=0.0003$) and BIRADS 0 ($p=0.09$), but not BIRADS 4/5 or abnormal breast exams. Navigation shortened the time for both colorectal ($p=0.0017$) and prostate screening resolution ($p=0.06$). Participant demographics included 72% minority, 49% with annual household income less than $10,000, and 36% uninsured.

Conclusions—Patient navigation positively impacts time to resolution of abnormal screening tests for breast, colorectal and prostate cancers in a medically underserved population.

Impact—By shortening the time to and increasing the proportion of patients with diagnostic resolution patient navigation could reduce disparities in stage at diagnosis and improve cancer outcomes.

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Keywords

patient navigation; disparities; cancer; abnormal screening tests

INTRODUCTION

Patient navigation programs are being increasingly adopted across the United States, although the evidence for their effectiveness is not well established (1). Patient navigation can potentially impact cancer care across the entire continuum, including screening rates, resolution of screening abnormality, diagnosis to initiation of treatment, treatment adherence and completion, survivorship and end-of-life care.

Most of the reported studies have assessed the impact of patient navigation on screening rates for breast, cervical and colorectal cancer (2–8). Fewer studies have been published on the effect of patient navigation on diagnostic resolution, treatment outcomes, survivorship and end-of-life (9).

The Patient Navigation Research Program (PNRP) was initiated in 2005 through funding from the National Cancer Institute's Center to Reduce Cancer Health Disparities. PNRP is a cooperative effort of nine health care institutions across the United States, serving medically underserved populations, including racial and ethnic minorities and those of low socioeconomic status (1,10). PNRP enrolled subjects with either an abnormal cancer screening finding or an incident diagnosis of breast, cervical, colorectal and prostate cancer. In this publication the authors describe the results of the individually randomized clinical trial conducted at the Denver PNRP, addressing subjects with abnormal screening findings.

METHODS

Setting

Denver Health is the public safety net for the City and County of Denver and has a long and distinguished record for serving as the healthcare provider for Denver's underserved populations. One quarter of Denver residents, or approximately 160,000 adults and children receive their care at Denver Health, of whom 57% are Hispanic, 18% Black and 20% White. In terms of insurance status, 46% of Denver Health patients are uninsured, 36% have Medicaid, 6% Medicare, 10% commercial and 2% are covered by the State Children's Health Insurance Program (SCHIP).

Denver PNRP conducted a prospective randomized clinical trial, one of two individually randomized trials within the National PNRP. The aims of the overall program were to (1) reduce the time from abnormal screening for breast, colorectal and prostate cancer to diagnostic resolution, (2) reduce the time from breast, colorectal and prostate cancer diagnosis to start of treatment, (3) increase adherence to cancer treatment, (4) increase patient satisfaction with care and (5) determine the cost effectiveness of patient navigation. Patient enrollment began at Denver Health in October 2006 and 1249 screening and treatment patients were enrolled in the study through June 2010. In this manuscript we report our findings for aim 1.

Study participants

Eligibility for Denver PNRP included an abnormal breast, colorectal or prostate screening test or a new diagnosis of these cancers. Breast screening tests included an abnormal clinical breast examination that resulted in a referral to a specialist or an abnormal mammogram that resulted in further diagnostic examination. Colorectal screening included a positive fecal occult blood test, an abnormal rectal examination, history of bright red blood in the stool among those 40 and over, or an abnormal sigmoidoscopy. Men enrolled with an abnormal prostate screening test had an abnormal prostate finding on digital rectal examination or an elevated PSA (≥ 4 ng/ml). Individuals with a prior history of cancer (excluding non-melanoma skin cancer) within the past 5 years, prior receipt of patient navigation, pregnancy or incarceration were not eligible for this study.

Recruitment, Consent and Randomization

Potentially eligible patients were identified through weekly electronic lists of patients meeting the criteria from the referral systems and laboratory and radiology results. The recruiter verified eligibility through the electronic medical record. Informational study materials were sent to patients by mail, and a follow-up call was made to obtain verbal consent and baseline information from all patients. Eligibility was confirmed during the initial telephone contact. Patients providing verbal consent and HIPAA authorization were then randomly assigned to either navigation or control groups, using a computer-generated algorithm stratified by cancer type. Navigated patients provided written consent and HIPAA authorization; a waiver for written consent and HIPPA authorization was obtained for the control subjects. Study IRB approval was provided by the Colorado Multiple Institution Review Board (COMIRB) prior to study initiation.

Participants assigned to the control group received a letter informing them of their group assignment status and then received usual care with no additional contact until the post-intervention survey administration. Those assigned to the navigation group received an introductory call from a patient navigator within three days of assignment.

Charlson Comorbidity Index

The Charlson comorbidity index is widely used and was developed to identify eighteen comorbid illnesses that increase the risk of 1-year mortality in a cohort of internal medicine inpatients (11).

Definition of Time to Resolution

Time to resolution was determined from the date of abnormal screening test to the date of definitive diagnosis. Study subjects without diagnostic resolution were censored at 365 days. Definitive diagnosis of a cancer was defined as the pathologic diagnosis of an invasive cancer on biopsy.

Navigation Intervention

The conceptual framework used for this intervention is an expansion of Wagner's Chronic Care Model (CCM) first implemented at Denver Health in 1999 (12). The CCM has three

main themes: evidence-based, population-based, and patient centered care. It is operationalized through six components: (1) Health System and Organization Change, (2) Delivery System Redesign, (3) Decision Support for Health Care Professionals, (4) Clinical Information Systems, (5) Self-Management Support, and (6) Community Resources. The CCM model has been expanded to the Comprehensive Care Model, and is utilized to guide care throughout Denver Health's Community Health Centers. This model includes the innovative use of patient navigators to promote diagnostic follow-up and to enhance patient/provider interactions. Within this model, the navigators use a strengths-based approach in navigator/patient interactions to identify assets available to patients while traversing the cancer diagnostic and treatment experience.

Patient navigator contact with patients was by phone (63%), email (8%), or in person (29%), depending on patient needs and preferences. A common patient log for navigators was developed to document their work and to capture each patient contact and the activities completed for the patient, along with the duration of each encounter. Patient navigators documented barriers to care from a pre-defined list, as well as actions taken to address these barriers.

During the initial patient contact, the navigator provided an introduction to navigation services and to the navigator's role. Next, the navigator elicited from the patient their potential and current barriers to completing the diagnostic test or treatment. The navigator monitored the patient during the entire diagnostic phase through resolution or, if a cancer diagnosis occurred, continuing through active cancer treatment. The navigator maintained contact with the patient by phone, home visits and in-person meetings at the medical center. Through ongoing patient contacts, the navigator continued to assess practical barriers, social support and intention to complete the recommended course of care.

Within the health care system, the patient navigator ensured that the required examinations were scheduled and communicated with clinic staff regarding patient needs and concerns. The navigator accompanied patients to their appointments when fear, social support and language barriers were identified, or if requested.

After each diagnostic test or examination, the patient navigator assessed patient understanding of results and linked the participant to clinic staff as needed for further explanation and to address concerns. If additional examinations were required, the navigator scheduled the appointments and ensured that the appointments were convenient for the patient. If the initially abnormal screening test was resolved with a non-cancer diagnosis, the navigator verified patient understanding of surveillance recommendation and terminated navigation services.

Denver Health PNRP employed three patient navigators. Navigator demographic and training information, including any personal experience with cancer, were collected from each navigator for identification of specific characteristics of navigators associated with successful navigation. All navigators attended an annual training conference designed and delivered by the American Cancer Society and the PNRP (13). In addition, frequent institution-based training sessions were conducted on clinical and psychosocial topics.

Patient navigators met with the program manager on a weekly basis initially and then continued to meet monthly throughout the research program. Patient navigators also met with clinical staff for training and feedback on medical questions and patient care. A clinical psychologist met regularly with the patient navigators to assist them in working with patients with various behavioral health conditions, as well as in motivating patients and maintaining professional boundaries.

Statistical Analysis

Demographic and clinical characteristics were compared using a Cochran-Mantel-Haenszel statistics for ordinal variables, Pearson's chi-square test of independence for nominal variables, as well as independent T-tests for continuous variables.

The effect of navigation on the time to resolution of screening was compared using a stratified log-rank test. The six strata were abnormal clinical breast exam, BIRADS 0 (additional imaging required), BIRADS 3 (short interval recommended for follow-up mammogram), BIRADS 4 (suspicious abnormality found requiring biopsy follow-up) or BIRADS 5 (highly suspicious for malignancy), colorectal and prostate. The log-rank test was specified a priori; the strata were later identified based on sample size, location and typical recommendations (e.g., immediate or six month follow-up). Test of effect modification utilized a Cox regression model with separate baseline hazards for the same six strata. Visual inspection of Kaplan-Meier plots suggested that the hazard associated with navigation was not constant over time. Time-varying indicator variables were defined for 0–90, 90–180 and 180+ days; and testing confirmed the hazard was not constant across these intervals (Wald Chi2 (2df)=21.1, $p<0.001$). Effect modification was tested based on interactions of centered covariates with the three time varying indicators in models that included the covariate as a main effect.

RESULTS

A total of 3,000 abnormal screening subjects were identified as potentially eligible from laboratory and radiology lists and on initial review. Of these, 1924 were excluded, 1162 due to not meeting study inclusion criteria, 327 declined to participate and 435 were unable to be contacted. A total of 1076 eligible abnormal screening subjects entered into the Denver PNRP from October 2006 through June 2010 were equally randomized to either the navigation intervention (n=538) or the control (no navigation) arm (n=538). Among the subjects in the intervention group, 38 did not receive the intervention due to identification of ineligibility (5 subjects) or refusal to submit written consent and authorization (33 subjects). In the control group, 25 subjects did not receive the intervention due to ineligibility (8 subjects) and refusal to provide consent and authorization (18 subjects). Only one navigated subject revoked consent and authorization.

The final analytical sample (993 subjects) included 485 navigated and 508 control subjects. Fourteen navigated and four control subjects were excluded in the final group due to issues related to medical records data and data collection. See CONSORT diagram (Fig. 1) for screening subject allocation and follow-up. Results of the time to resolution of abnormal screening tests for breast (n=628), colorectal (n=235) and prostate cancer (n=130) are

described in this report. Of the 628 randomized subjects with abnormal breast screens analyzed, 66 had abnormal clinical breast examinations and 304 had BIRADS 0, 200 BIRADS 3, 58 BIRADS 4 or 5 mammographic abnormalities. Results for the impact of patient navigation on newly diagnosed cancer patients will be reported separately.

Characteristics of Study Participants

The baseline characteristics for the enrolled subjects are shown in Table 1. Overall demographics were notable for high minority representation (53% Hispanic, 24% White, 19% Black), a high percent of primarily Spanish speakers (30%), low education attainment (40% with some high school or less); low annual household income (less than $10,000 in 49%), high unemployment (65%), and high uninsured rate (36%). These and other baseline subject characteristics were well balanced between the control and intervention arms.

Time to Resolution – Overall

Time to resolution for all cancer screening combined was significantly shorter in the navigated group, (stratified log rank test, $p<0.001$). From visual inspection of Kaplan-Meier plots (Figures 2 & 3), navigation especially improves adherence to 6-month follow-up for the breast screening population, as demonstrated most clearly in the BIRADS 0 and BIRADS 3 groups, while the impact of navigation in colorectal and prostate screening was most pronounced in the 3–6 month period. Details for each stratum are described below.

Time to Resolution – Breast Cancer Screening

Figure 2 shows the Kaplan Meier plots for time to resolution by navigation versus control arms for the mammographic abnormalities BIRADS 0 and BIRADS 3 at time of enrollment. Benefit was found especially in subjects presenting with mammographic BIRADS 3 ($p=0.0003$), was of borderline significance for patients with mammographic BIRADS 0 ($p=0.09$), but was not significant for those with BIRADS 4/5 or abnormal clinical breast examinations (not shown).

Time to Resolution – Colorectal Cancer Screening

Figure 3 shows the Kaplan-Meier plot for time to resolution of abnormal screening test for colorectal cancer by navigation versus control arms. Navigation significantly shortened the time for colorectal screening resolution ($p<0.002$).

Time to Resolution – Prostate Cancer Screening

Figure 3 also shows the Kaplan-Meier plot for time to resolution of abnormal screening for prostate cancer by navigation versus control arms. There is a strong trend for navigation to shorten the time for prostate cancer screening resolution ($p<0.01$), although the confidence intervals for point estimates over the entire range of follow-up displayed in Figure 3 do overlap.

Effect Modification

Effect modification was tested using interactions of covariates with the three time-varying indicators of time in models that included the covariate as a main effect. There were no

significant main effects by age, language, marital status, insurance, gender (for colorectal), number of baseline barriers and comorbidity; nor was there evidence that these patient characteristics modified the effect of navigation.

Adherence Outcomes

Patients in the navigated group were more likely to complete diagnostic follow-up and resolution of initial abnormal screening tests as compared to the control patients. As can be seen in Table 2, with all three cancer screening sites combined, diagnostic resolution was achieved in 88% versus 70% in the navigated versus control groups, respectively ($p<0.001$). For the abnormal breast screening group, 92% of the navigated patients reached diagnostic resolution of the initial abnormal test, as compared to 77% for the control patients ($p<0.001$). For the abnormal colorectal screening group, 79% reached diagnostic resolution in the navigated group versus 58% in the control group ($p<0.002$), and for the abnormal prostate screening group, diagnostic resolution for the navigated group was 84% as compared to 64% in the control group ($p=0.01$).

Number and Stage of Cancers Detected

The number of cancers diagnosed for each cancer screening group was similar (Table 2), and the stage at which these cancers were diagnosed did not differ significantly between navigated and control groups (not shown). Although there were more cancers diagnosed in the navigated prostate screening group (23 patients) as compared to the control group (17 patients), this was not statistically significant due to the lower number of prostate screening patients.

DISCUSSION

Although study designs differed among the ten PNRP participating institutions, the major aims and outcomes were the same. For assessing time to resolution of an abnormal screening finding, the Denver PNRP was the only one of the participating institutions with an individually randomized study design, while other institutions utilized group-randomized or prospective cohort controls. The results of our prospectively randomized controlled trial show that patient navigation positively impacts the time to resolution of abnormal screening tests for breast, colorectal and prostate cancers in a medically underserved population, and significantly improves the percent of patients reaching diagnostic resolution.

A number of prior studies have reported that patient navigation resulted in improved resolution of mammographic screening abnormality, ranging from 21%–29% when compared to control subjects (reviewed by Wells et al, 2008 (1) and Paskett et al, 2011 (14)). However, only 2 of 8 reported studies randomly assigned subjects to a patient navigation and a no-navigation control group (9,15). The study by Ell et al randomized women with abnormal mammograms to either the navigation intervention group (96 women) or no-navigation control group (108 women). Their results showed that the intervention group was more likely to be adherent through diagnostic resolution than the control group (90% versus 66%, OR=4.48, $p<0.001$) (15). In the study by Ferrante et al, 55 subjects were randomized to the navigation intervention and 50 to usual care. Women in the

navigation group had shorter times to diagnostic resolution (mean of 25 vs. 43 days, p=0.001) with 94% of navigated patients achieving diagnostic resolution vs. 78% in the control group (9).

These results are of similar magnitude to those reported in our study, namely diagnostic resolution rates of 92% for navigated patients with abnormal mammographic findings as compared to 77% for control patients. In our study, the benefits from navigation were especially striking for patients with initial BIRADS 3 mammographic abnormalities, and to a lesser extent in those with BIRADS 0, where we saw a significant improvement in the adherence rates to the recommended 6-month repeat mammogram in the control group (80% versus 60% resolution at 240 days). BIRADS 4 and 5 patients, on the other hand, saw rapidly rising and high diagnostic resolution rates in both navigated and control groups (85% and 80%, respectively, at 90 days), most likely driven by the urgency of the serious mammographic abnormalities reflected by this group of patients.

This is among the first publication, to our knowledge, of a randomized controlled trial evaluating the impact of patient navigation on the diagnostic resolution in patients with abnormal screening tests for colorectal cancer (2,3) and is the first for prostate cancer navigation. As with our patients with abnormal mammograms, we found that patient navigation shortens the time to diagnostic resolution and significantly increased the proportion of patients adherent through diagnostic resolution for colorectal screening abnormalities (positive fecal occult blood, rectal bleeding, abnormal digital rectal examination or sigmoidoscopy). For patients with prostate cancer screening abnormalities (elevated PSA, abnormal digital rectal examination), navigation led to improvement in time to and in percent completing diagnostic resolution, although to a somewhat lesser degree than for patients with colorectal cancer screening abnormalities. This is most likely due to the smaller numbers enrolled and a lower sense of urgency in evaluating these abnormalities by both patients and providers.

The populations studied by Ell et al and Ferrante et al included a large proportion of minority patients, as did our study population (9,15). All three populations are notable for low annual household income, low education attainment, high unemployment, high uninsured rate, and high comorbidity. These populations encounter numerous barriers to accessing and maintaining health care, including the timely resolution of abnormal cancer screening findings (16,17). Patient navigation is designed to assist patients to overcome these barriers, provide a safe, non-threatening forum for deliberation, and lend emotional support to patient decision-making and dealing with an adverse screening outcome.

Study strengths include the use of a prospective individually randomized controlled clinical trial design, large number of patients enrolled compared to prior studies, a high enrollment rate of 77% among subjects able to be contacted, and utilization of a centralized electronic medical record system to identify potential participants and to document study outcomes. We enrolled significant numbers into the breast (628) and colorectal (235) cancer abnormal screening components of the study, with fewer patients with abnormal prostate screening (130). Our results are especially applicable to other safety net health care settings in light of

our largely minority, low income and uninsured study population, with multiple challenges in their ability to adhere to demanding diagnostic evaluations.

An additional strength included consistent interpretation of screening mammograms by two mammographers over the 4 years of participant enrollment. The percent of BIRADS 0 and 3 remained stable over that period, although the percentages of readings falling into these 2 categories were consistently higher than at other participating institutions. We also experienced little staff turnover and were able to retain a cadre of experienced navigators throughout.

Limitations of this study include the delay between identifying eligible patients, contacting them for consent, enrolling them into the study, and initiating the intervention. Our electronic medical record greatly assisted in the identification of potentially eligible patients; however, up-to-date contact information was not always available. In addition, the intervention could not be initiated until consent had been obtained. This delay to enrollment and initiation of the navigation or control intervention was similar for both groups; mean of 36.6 days (SD+/−28.3) for the navigated group versus mean of 34.1 days (SD+/−26.4) for the control group. It is possible that this delay blunted the impact of navigation during the early part of patients' dealing with the abnormal screen results. In future studies, methods need to be explored to shorten this delay, allowing for earlier intervention to further improve outcomes.

A second limitation is the relatively small number of patients entered into the study with abnormal prostate cancer screening findings. Screening practice has undergone changes over the past decade, resulting in fewer men being screened for prostate cancer, especially in the older age groups (18). Although our study still suggests a benefit for the abnormal prostate cancer screening patients, the smaller numbers resulted in borderline statistical significance.

Patient navigation is an effective strategy for improving adherence to diagnostic evaluation and resolution, regardless of ethnicity, insurance status and education level. Our study provides additional evidence of its effectiveness in patients with abnormal mammographic findings and provides new information in patients with abnormal screening results for colorectal and prostate cancer in an underserved patient population.

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References

1. Wells KJ, Battaglia TA, Dudley, Garcia R, Greene A, Calhoun E, et al. Patient Navigation: State of the art or is it science? CANCER. 2008; 113(8):1999–2010. [PubMed: 18780320]
2. Lasser KE, Murillo J, Lisboa BA, Casmir AN, Valley-Shah L, Emmons KM, et al. Colorectal cancer screening among ethnically diverse, low-income patients. Arch Int Med. 2011; 171(10):906–912. [PubMed: 21606094]

3. Percac-Lima S, Grant RW, Green AR, Ashburner JM, Gamba G, OO S, et al. A culturally tailored navigator program for colorectal cancer screening in a community health center: A randomized controlled trial. J Gen Int Med. 2009; 24(2):211–217.
4. Taylor VM, Jackson JC, Yasui Y, Nguyen TT, Woodall E, Acorda E, et al. Evaluation of a cervical cancer control intervention using lay health workers for Vietnamese American women. Am J Public Health. 2010; 100:1924–1929. [PubMed: 20724673]
5. Nguyen TT, McPhee SJ, Gildengorin G, Nguyen T, Wong C, Lai KQ, et al. Papanicolaou testing among Vietnamese Americans: Results of a multifaceted intervention. Am J Prev Med. 2006; 31:1–9. [PubMed: 16777536]
6. Ahmed NU, Haber G, Semenya KA, Hargreaves MK. Randomized controlled trial of mammography intervention in insured very low-income women. Cancer Epidemiology, Biomarkers & Prevention. 2010; 19:1790–1798.
7. Christie J, Itzkowitz S, Lihau-Nkanza I, Castillo A, Redd W, Jandorf L. A randomized controlled trial using patient navigation to increase colonoscopy screening among low income minorities. J Natl Med Assoc. 2008; 100:278–284. [PubMed: 18390020]
8. Jandorf L, Gutierrez Y, Lopez J, Christie J, Itzkowitz SH. Use of a patient navigator to increase colorectal screening in an urban neighborhood clinic. J Urban Health. 2005; 82:216–224. [PubMed: 15888638]
9. Ferrante JM, Chen P-H, Kim S. The effect of patient navigation on time to diagnosis, anxiety, and satisfaction in urban minority women with abnormal mammograms: A randomized controlled trial. J Urban Health. 2008; 85(1):114–124. [PubMed: 17906931]
10. Freund KM, Battaglia TA, Calhoun E, Dudley DJ, Fiscella K, Paskett E, et al. National Cancer Institute Patient Navigation Research Program: methods, protocol and measures. CANCER. 2008; 113:3391–3399. [PubMed: 18951521]
11. Charlson ME Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. J Chronic Dis. 1987; 40:373–383. [PubMed: 3558716]
12. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? Effective Clinical Practice. 1998; 1:2–4. [PubMed: 10345255]
13. Calhoun EA, Whitley EM, Esparza A, Ness E, Valverde PA, Greene A, et al. A national patient navigator training program. Health Promotion Practice. 2010; 11(2):205–215. [PubMed: 19116415]
14. Paskett ED, Harrop P, Wells KJ. Patient navigation: an update on the state of the science. CANCER. 2011; 61(4):237–249.
15. Ell K, Vourlekis B, Lee PJ, Xie B. Patient navigation and case management following an abnormal mammogram: A randomized clinical trial. Prev Med. 2007; 44:26–33. [PubMed: 16962652]
16. Raich, PC.; Valverde, P.; Thorland, W.; Kilbourn, K.; Risendal, B.; Borrayo, E.; Whitley, E. The relationship between patient co-morbidities and perceived barriers in a group of underserved patients with cancer or at risk for cancer. Poster presentation at the 30th annual meeting of the Society of Behavioral Medicine; April 25, 2009; Montreal, Canada. (Poster #D-28).
17. Valverde, P.; Thorland, W.; Risendal, B.; Whitley, E.; Raich, P. Gender differences in barriers experienced by low-income participants of a patient navigator clinical trial. Poster presentation at the annual meeting of the American Association of Cancer Research; February 3–6, 2009; Phoenix, AZ.
18. Chou R, Croswell JM, Dana T, Bougatsos C, Blazina I, Rongwei F, et al. Screening for prostate cancer: a review of the evidence for the U.S. Preventive Services Task Force. Ann Int Med. 2011; 155:762–771. [PubMed: 21984740]

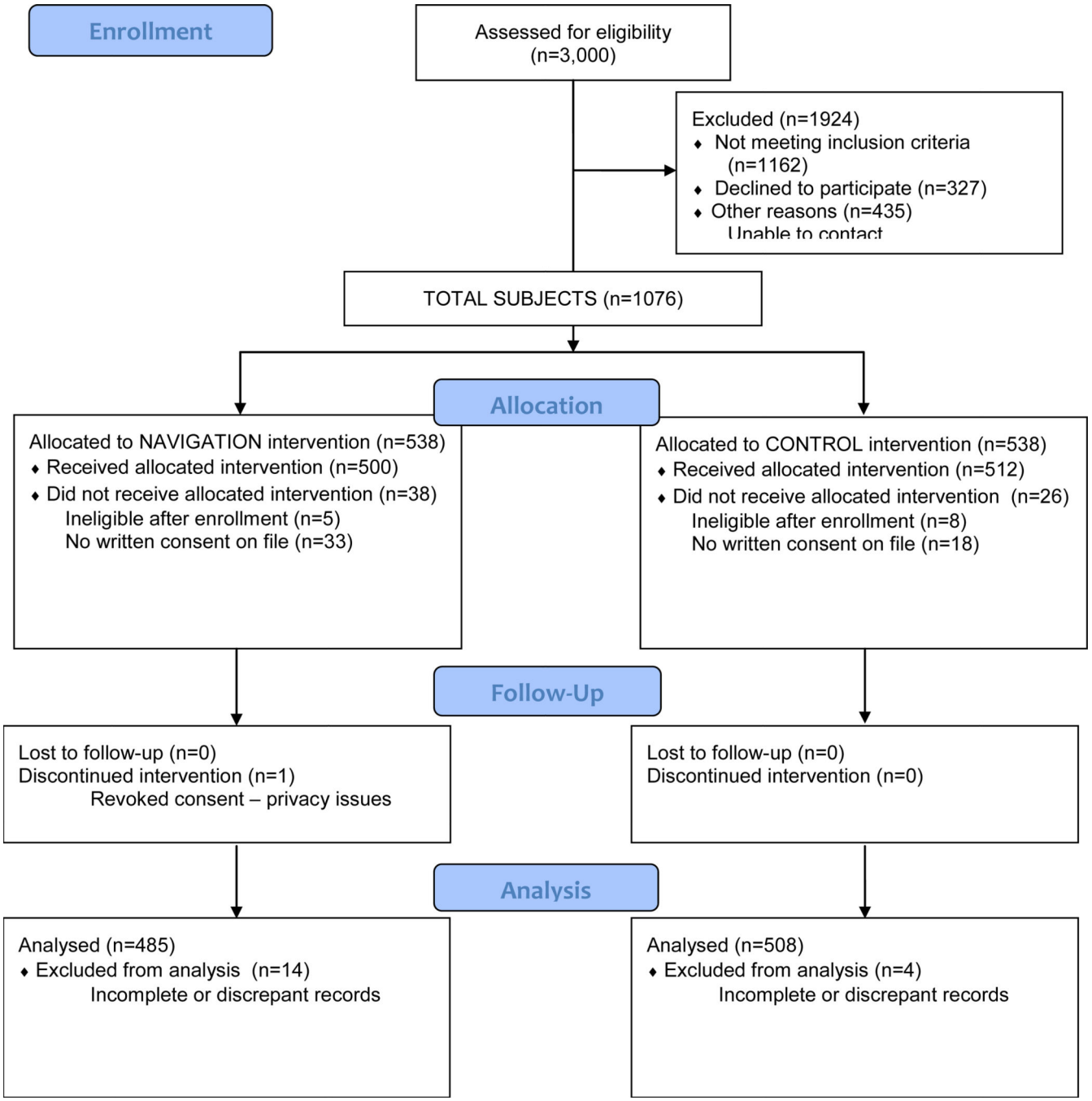

Fig. 1.
CONSORT Flow Diagram of Screening Patients

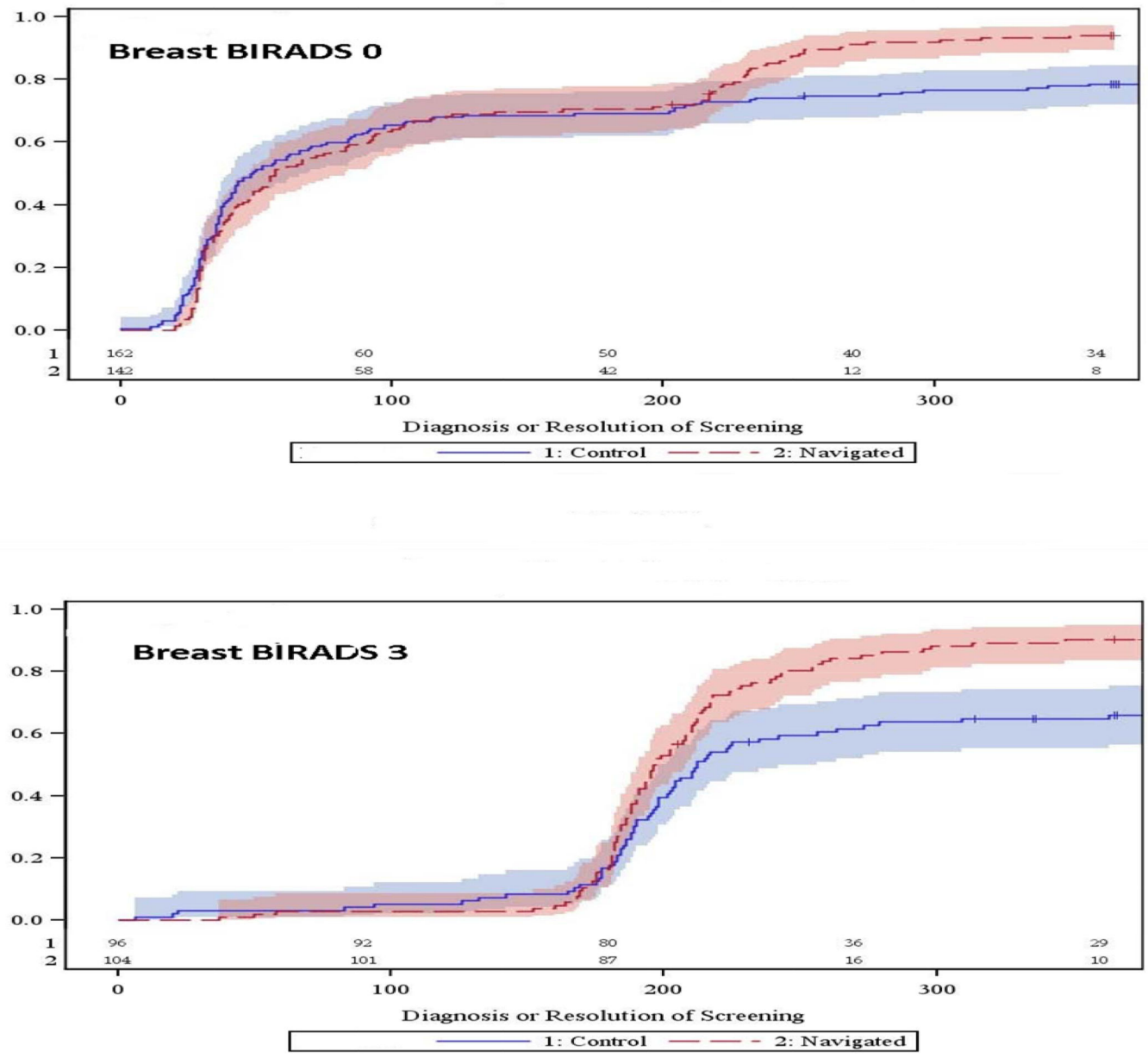

Fig. 2.

Kaplan-Meier Estimates for Proportion of Subjects with Resolution by Days from Initial Screening: Breast Screening Subjects – BIRADS 0 and BIRADS 3

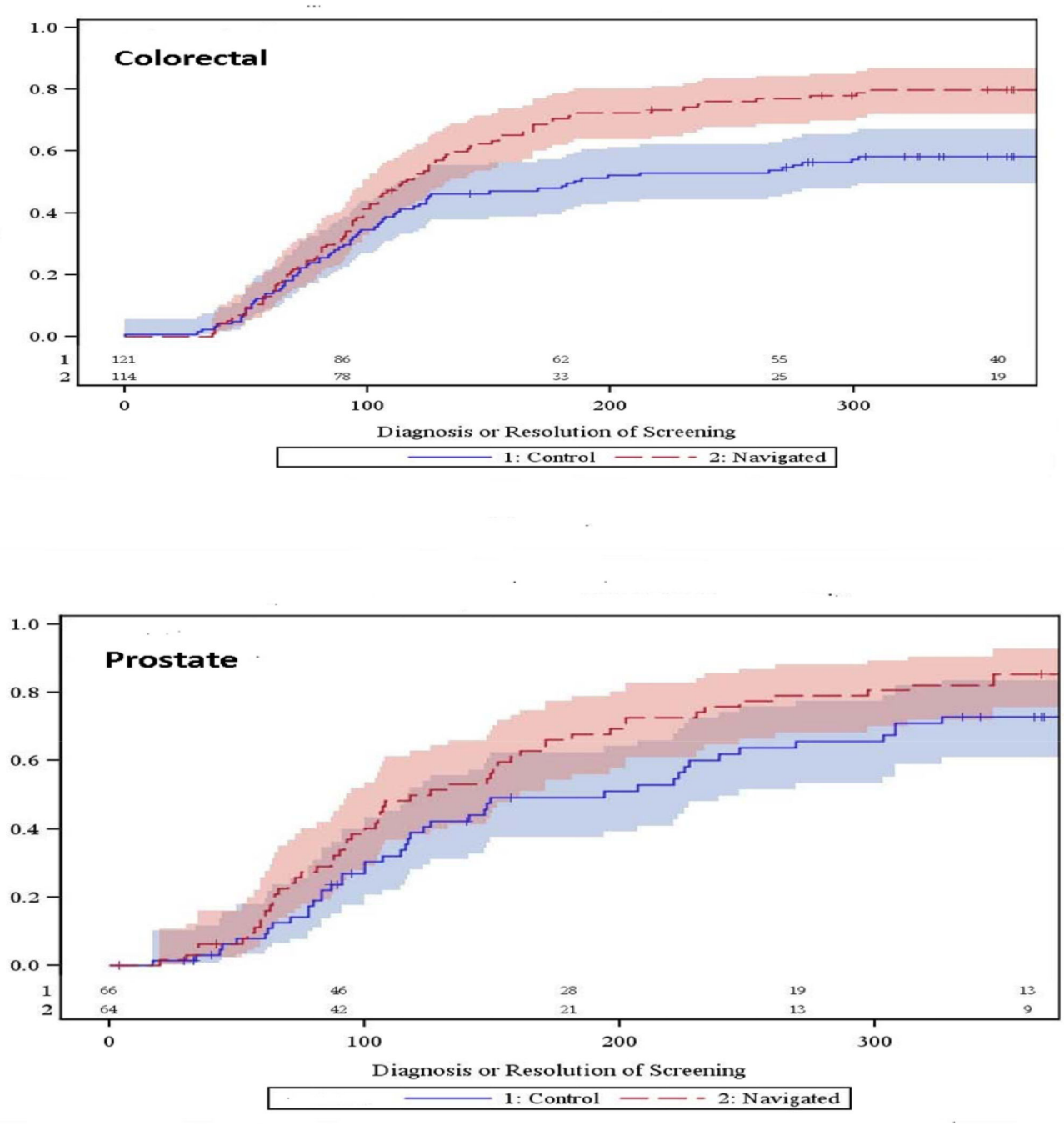

Fig. 3.

Kaplan-Meier Estimates for Proportion of Subjects with Resolution by Days from Initial Screening: Colorectal and Prostate Screening Subjects

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Table 1

Baseline Demographics of Study Population

Variable	Level	Navigated		Control		Combined		p
		Count	%	Count	%	Count	%	
Sex	Male	118	24	141	28	259	26	0.22
	Female	367	76	367	72	734	74	
Age (yrs)	<30	16	3	10	2	26	3	
	30–39	56	12	53	10	109	11	
	40–49	145	30	160	31	305	31	
	50–59	141	29	147	29	288	29	0.77
	60–69	91	19	103	20	194	20	
	70+	36	7	35	7	71	7	
	NoAnswr/Msg	0	0	0	0	0	0	
Race/Ethnicity	White	122	25	119	23	241	24	
	Black	96	20	97	19	193	19	
	Hispanic	250	52	275	54	525	53	0.78
	Other	17	4	16	3	33	3	
	NoAnswr/Msg	0	0	1	0	1	0	
Cancer Site	Breast	308	64	320	63	628	63	
	Colorectal	114	24	121	24	235	24	0.99
	Prostate	63	13	67	13	130	13	
Navigation Group	Navigated	485	100	0	0	485	49	
	Control	0	0	508	100	508	51	
Prev. Navigation	No	484	100	501	99	985	99	
	Yes	0	0	1	0	1	0	0.11
	NoAnswr/Msg	1	0	6	1	7	1	
Language	English	330	68	335	66	665	67	0.71
	Spanish	142	29	156	31	298	30	

Variable	Level	Navigated		Control		Combined		p
		Count	%	Count	%	Count	%	
	Other	13	3	17	3	30	3	
Education	Some HS or less	194	40	201	40	395	40	0.17
	HS Grad / GED	134	28	125	25	259	26	
	Some College/AA	106	22	112	22	218	22	
	College Grad	34	7	34	7	68	7	
	Grad/Prof Degree	7	1	20	4	27	3	
	NoAnswr/Msg	10	2	16	3	26	3	
Employment	None/Rtrd/Dsabld	312	64	332	65	644	65	0.56
	Part Time	77	16	81	16	158	16	
	Full Time	95	20	91	18	186	19	
	NoAnswr/Msg	1	0	4	1	5	1	
Marital Status	Single/Nvr Married	129	27	127	25	256	26	0.51
	Married/w Partner	168	35	194	38	362	36	
	Dvrcd/Sprtd/Wdwd	188	39	187	37	375	38	
	NoAnswr/Msg	0	0	0	0	0	0	
Household Size	1	153	32	151	30	304	31	0.20
	2	151	31	133	26	284	29	
	3	48	10	65	13	113	11	
	4	55	11	62	12	117	12	
	5+	78	16	95	19	173	17	
	NoAnswr/Msg	0	0	2	0	2	0	
Household Status	Own Home	126	26	135	27	261	26	0.31
	Rent	283	58	279	55	562	57	
	w/ Friends or Family	51	11	62	12	113	11	
	Other	3	1	5	1	8	1	
	Asstd/Group Home	6	1	6	1	12	1	
	Homeless	14	3	11	2	25	3	

Variable	Level	Navigated		Control		Combined		p
		Count	%	Count	%	Count	%	
	NoAnswr/Msg	2	0	10	2	12	1	
Household Income	<$10,000	251	52	235	46	486	49	0.53
	$10,000–19,999	122	25	149	29	271	27	
	$20,000–29,999	47	10	57	11	104	10	
	$30,000–39,999	23	5	29	6	52	5	
	$40,000–49,999	8	2	5	1	13	1	
	$50,000+	26	5	26	5	52	5	
	NoAnswr/Msg	8	2	7	1	15	2	
Insurance Status	Private	52	11	60	12	112	11	0.65
	Public	265	55	263	52	528	53	
	Uninsured	168	35	185	36	353	36	
	NoAnswr/Msg	0	0	0	0	0	0	

Variable	Navigated		Control		Combined		p
	Mean	SD	Mean	SD	Mean	SD	
Charlson Comorbidity Index Score	1.1	1.9	1.1	1.7	1.1	1.8	0.78
Number of Months in Study	6.64	6.59	7.08	6.24	6.87	6.42	0.28

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Table 2

Definitive Tests and Diagnostic Resolution

		Navigated		Control		
Site	**Test**	**Count**	**%**	**Count**	**%**	**p**
All						
	No Cancer	388	80%	324	63%	<0.001
	No Resolution	58	12%	150	30%	
	Cancers Diagnosed	39	8%	34	7%	0.42
	TOTAL	485		508		
Breast						
	Excisional biopsy	8	3%	8	3%	
	Stereotactic core biopsy	18	6%	20	6%	
	US-guided core biopsy	23	7%	23	7%	
	Core biopsy w/o imaging guidance	2	1%	2	1%	
	Fine needle aspiration biopsy	0	0%	1	0%	
	Breast MRI	0	0%	0	0%	
	Breast US	61	20%	57	18%	
	Diagnostic mammogram	165	54%	126	39%	
	Clinical assessment	0	0%	2	1%	
	Other	7	2%	6	2%	
	Total Resolved	284	92%	245	77%	<0.001
	No resolution	24	8%	75	23%	
	Cancers Diagnosed	13	4%	12	4%	0.76
	TOTAL	308		320		
Colorectal						
	Colonoscopy w/ biopsy	54	47%	36	30%	
	Sigmoidoscopy w/ biopsy	0	0%	1	1%	
	Colonoscopy w/o biopsy	29	25%	28	23%	

Site	Test	Navigated Count	Navigated %	Control Count	Control %	p
	Sigmoidoscopy only	1	1%	3	2%	
	Virtual colonoscopy	0	0%	0	0%	
	Barium enema	0	0%	0	0%	
	Other	6	5%	2	2%	
	Total Resolved	90	79%	70	58%	<0.002
	No resolution	24	21%	51	42%	
	Cancers Diagnosed	3	3%	5	4%	0.53
	TOTAL	114		121		
Prostate						
	TRUS-guided biopsy	42	67%	34	51%	
	Ultrasound	0	0%	0	0%	
	Follow-up PSA	3	5%	1	1%	
	Clinical assessment	5	8%	7	10%	
	Other	3	5%	1	1%	
	Total Resolved	53	84%	43	64%	0.01
	No resolution	10	16%	24	36%	
	Cancers Diagnosed	23	37%	17	25%	0.17
	TOTAL	63		67		

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