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Patient Navigation to Increase Colorectal Cancer Screening among Latino Medicare Enrollees: A Randomized Controlled Trial

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Abstract

Purpose—Latino Medicare enrollees report suboptimal rates of colorectal cancer screening (CRCS) despite Medicare policies designed to improve CRCS access for older persons. Patient

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navigation (PN) may address many underlying barriers to CRCS, yet little is known about the effectiveness of PN to increase CRCS adherence among Latino Medicare enrollees.

Methods—Using a randomized controlled trial study design, we evaluated tailored PN delivered outside of primary care settings as an intervention to increase CRCS adherence in this population. Intervention participants (n=135) received tailored PN services which included education, counseling and logistical support administered in their language of choice. Comparison participants (n=168) received mailed cancer education materials. We compared CRCS rates between interventions and used multivariable logistic regression to assess the odds of CRCS adherence for PN versus comparison groups after adjusting for covariates of interest.

Results—More navigated than non-navigated participants became CRCS adherent during the study period (43.7% versus 32.1%, $P=0.04$). The odds of CRCS adherence were significantly higher for PN relative to comparison participants before and after adjusting for covariates (unadjusted OR: 1.64, $P=0.04$; adjusted OR: 1.82, $P=0.02$). Higher CRCS adherence rates were observed primarily in the uptake of endoscopic screening methods.

Conclusions—This study demonstrates that PN delivered outside of the primary care environment is modestly effective in increasing CRCS adherence among Latino Medicare enrollees. This intervention strategy should be further evaluated as a complement to primary care-based PN and other care coordination strategies to increase adherence with CRCS and other evidence-based screenings among older Latinos.

INTRODUCTION

Colorectal cancer (CRC) is the second most commonly diagnosed cancer among Latinos, with the majority of new cases concentrated among Latinos aged 65 years and older.[1] Appropriate CRC screening (CRCS) reduces mortality by facilitating the removal of precancerous polyps and detection of CRC in its localized stage, when the 5-year survival rate for CRC is highest.[1,2] Yet, less than half (47.0%) of age-eligible Latinos in the United States (U.S.) were adherent to the recommended CRCS guidelines in 2010 – a rate well below the national average (61.5%) and Healthy People 2020 target (70.5%).[1,3]

A key predictor of CRCS adherence is health insurance coverage, an important facilitator of access to care.[4–7] Screening adherence rates remain suboptimal, however, even among older Latinos who are eligible to receive CRCS through Medicare, a nearly universal health insurance program for older Americans.[6–8] Disparities between Latino and non-Latino white Medicare enrollees in CRCS[7–9] and early stage CRC diagnosis[1,9] have persisted or widened over time, despite Medicare policy changes aimed at increasing CRCS adherence. These disparities are associated with multiple socioeconomic and cultural barriers faced by Latinos, including low educational attainment, high poverty rates, neighborhood segregation, non-U.S. nativity, perceived discrimination, mistrust of healthcare providers, and factors related to language and communication.[3,10] Overall lack of awareness about CRCS and beliefs that it is unnecessary are also key reasons for nonadherence among older Latinos.[7,10–12]

Patient navigation (PN) is an intervention designed to address CRCS disparities in vulnerable populations. In addition to providing relevant patient education (e.g., written

materials, discussion of screening methods), PN is used to coordinate care across the cancer continuum through individualized psychosocial and logistical support (e.g., scheduling appointments, completing paperwork, managing financial/insurance issues, addressing language or cultural barriers to effective patient-provider interactions).[13–15] However, more information is needed about specific intervention characteristics (e.g., setting, timing of PN delivery within the referral process, screening methods promoted) that are associated with improved screening adherence so that PN may be targeted to subgroups that will derive the most benefit.[15,16]

Latino Medicare enrollees are an important target for PN aimed at increasing CRCS adherence because of the disparities that persist in this population. These disparities may be partially driven by lower rates of primary care provider (PCP) utilization among Latino Medicare enrollees.[17,18] Furthermore, preventive and primary care use varies significantly across Latino subgroups in the U.S. based on differences in ancestry, geographic residence and other factors, with Latinos of Mexican ancestry being less likely than other Latinos to visit a physician each year.[18,19] PCP access and utilization are directly related to CRCS adherence.[4,6,7,9] Some Latino Medicare enrollees, therefore, may miss opportunities to receive PN initiated in PCP settings.

Previous randomized controlled trials (RCTs) have evaluated PN delivered *inside* PCP settings to increase CRCS adherence,[20–27] but none to our knowledge have focused on Latino Medicare enrollees *outside* of PCP settings. In this study, we evaluate PN delivered outside of PCP settings as an intervention to increase CRCS adherence among Latino Medicare enrollees in the southwestern U.S., hypothesizing that individuals who received PN would have higher CRCS adherence rates than individuals who received written CRC education materials only. As a secondary objective, we explored whether PN was associated with higher CRCS adherence based on the screening method used (e.g., endoscopy versus fecal occult blood test, FOBT).

METHODS

Recruitment and Study Design

This demonstration project was conducted from March 2007 to December 2010 as a 2-arm (screening and treatment) RCT of PN designed and funded by the Centers for Medicare and Medicaid Services (CMS).[28] The project focused on delivering PN to reduce disparities in the screening, diagnosis and treatment of breast, cervical, colorectal, lung and prostate cancers. Medicare fee-for-service (FFS) enrollees recruited through 6 sites were eligible to participate in English and/or Spanish if they were ≥ 40 years and covered by Medicare Parts A and B.[28] Additionally, participants must not have been diagnosed with any type of cancer within the last 5 years to be included in the screening arm.[28] Participants were recruited using lists of Medicare enrollees provided by CMS and in-person contacts at community-based settings (e.g., libraries, health fairs, churches, senior centers). Participants provided written or verbal informed consent. Enrolled participants were randomly assigned by a CMS third party contractor to receive either PN services (intervention group) or mailed cancer education materials (comparison group). The study was approved by the Institutional Review Board at the University of Texas MD Anderson Cancer Center in February 2007.

For this study, we focused on CRCS adherence among screening arm participants at the University of Texas MD Anderson Cancer Center recruitment site who were nonadherent with US Preventive Services Task Force (USPSTF) CRCS guidelines upon project enrollment. The USPSTF recommends that individuals aged 50-to-75 years undergo regular CRCS using one of the following methods: FOBT at 1-year, flexible sigmoidoscopy at 5-year or colonoscopy at 10-year intervals.[2] Enrollees who reported being adherent with one of these methods at baseline were excluded from our analysis (Figure 1).

Intervention

Participants assigned to the intervention arm received tailored PN services designed to address possible misconceptions about CRC and CRCS, educate them about the screening tests available through Medicare and facilitate completion of their preferred CRCS test. The intervention was delivered by navigators fluent in English and Spanish. All navigators had a bachelor's degree in public health or a related field and 2 years of experience facilitating community-based support services or case management. The navigators received 80 hours of standardized training on core PN competencies (e.g., communication, service coordination, advocacy) and attended at least one 3-day continuing education conference sponsored by the American Cancer Society, National Cancer Institute and CMS.[29]

Participants' needs and applicable PN services were assessed using coded lists of barriers and services programmed into the study database. Automated prompts reminded navigators to query participants about their cancer screening histories, provide education about screening guidelines and Medicare's coverage of CRCS, and offer tailored PN services to address screening barriers assessed by the navigator. Most participants received individual-and/or family-level education (82%). Others also received support/counseling (70%), referrals/assistance (37%) and/or appointment scheduling/reminders (18%). Comparison participants were mailed educational materials outlining preventive services available through Medicare, describing risk factors and explaining the importance of adhering to recommended screening guidelines for CRC and other cancers. All participants were contacted at least once by mail (comparison group) or by phone and mail (PN group, range: 1 to 20, median=3).

Data Collection

Trained research staff collected self-reported data via phone or in-person interviews using Cancer Status Assessment surveys developed by CMS.[28] Baseline data were collected prior to randomization. Interviewers were not blinded to participants' group assignments during follow-up interviews. Surveys were administered to document participants' general health status, cancer screening histories and health system interactions. Barriers and PN service codes were recorded during and/or after each encounter. Data were reviewed regularly for completeness, accuracy and consistency. Participants received \$25 gift cards for each 45–60 minute interview.

Measures

We measured CRCS adherence according to USPSTF guidelines using self-reported data collected at the termination of the demonstration project (primary outcome). Participants

were read descriptions of CRCS test procedures and asked how long it had been since: “your last blood stool test using a home kit?” and “your last sigmoidoscopy or colonoscopy?” We created a dichotomous measure of CRCS adherence (no/yes). Individuals were considered CRCS adherent if they reported having received a FOBT within the past year or a colonoscopy or flexible sigmoidoscopy (COL/FS) at any time during their project participation. The combined COL/FS measurement used on the survey did not differentiate between the two endoscopic methods. However, it is adequate for these analyses because the demonstration project lasted <4 years. Reported uptake of either method during the study suggests CRCS adherence under USPTF guidelines. Dichotomous measures for FOBT and COL/FS adherence were created to assess CRCS adherence by test method.

Several variables were examined as potential confounders because of their association with health inequities or increased risk for CRC.[1,3] These covariates included: age (50-to-64 years or 65-to-75 years); gender; primary language (English or Spanish); US nativity; marital status; education; access to usual source of care (USOC) provider; self-rated health; personal history of irritable bowel disease; and family history of CRC. The primary reasons given by participants for their CRCS nonadherence at study onset were also examined.

Analysis

Descriptive statistics were used to summarize characteristics of the study sample. Differences between randomized groups were assessed using chi-square tests. Logistic regression models (unadjusted and adjusted) were used to estimate the effect of PN on the odds of being CRCS adherent at the end of the study. Final adjusted models included age, gender, education and USOC provider status. These variables were significantly associated with CRCS in bivariate analyses at the $P<0.15$ level or were deemed important for inclusion based on our literature review. Separate logistic models were used to estimate the odds of CRCS adherence by FOBT or COL/FS methods. The demonstration project was designed with 80% power to detect a 15 percentage point difference between study arms. All reported P -values were 2-sided, with statistical significance set at the 0.05 level. Analyses were conducted using Stata version 12 software (Stata Corp, College Station, TX).

RESULTS

The flow of patients through recruitment, randomization, and assessment of primary outcomes is illustrated in Figure 1. Of 2,084 eligible participants from the demonstration project, 1,044 were assigned to PN and 1,040 to the comparison group. Participants were excluded from the present study if they were age ineligible, were CRCS adherent at baseline, had developed cancer during the course of the demonstration project, did not provide baseline CRCS data (e.g., responded “don’t know” or refused to answer) or did not participate in the project for at least 6 months. A total of 303 participants (intervention: $n=135$, comparison: $n=168$) were included in the final complete case analysis of CRCS adherence reported here. On average, participants in both groups remained in the study 15.9 months ($SD=7.6$, $P=0.96$). There were no significant differences between groups with respect to socioeconomic, health status or CRC risk factors (Table 1). More than 60% of participants reported that their main reasons for CRCS nonadherence at baseline were lack

of knowledge (“didn’t know I needed this type of test”), physician’s recommendation (“doctor didn’t tell me I needed it”) or awareness (“no reason, never thought about it”), Figure 2.

More navigated than non-navigated participants became CRCS adherent during the observation period (43.7% versus 32.1%, $P=0.04$, data not shown). Differences were observed in the reported uptake of the COL/FS and FOBT methods, but were significant only for COL/FS (35.6% versus 23.8%, $P=0.03$, data not shown). The odds of CRCS adherence were significantly higher for PN relative to comparison participants before and after adjusting for covariates of interest (unadjusted OR: 1.64, $P=0.04$; adjusted OR: 1.82, $P=0.02$), Table 2. PN was associated with higher odds of COL/FS and FOBT, but the effect was significant only when examining COL/FS (unadjusted OR: 1.77, $P=0.03$; adjusted OR: 1.90, $P=0.02$).

DISCUSSION

The purpose of this study was to evaluate PN delivered outside the context of the PCP setting as an intervention to increase CRCS adherence among Latino Medicare FFS enrollees. By locating this intervention outside of the PCP setting and initiating PN prior to receipt of a physicians’ referral, we are inclusive of older Latinos who, despite having Medicare coverage, may not visit or receive CRCS recommendations from PCPs or other providers. We found a modest but significant difference in CRCS adherence rates between participants who received PN (43.7%) and those who received mailed educational materials (32.1%). Secondary analyses revealed that higher CRCS adherence rates for PN relative to comparison participants were driven primarily by uptake of COL/FS methods.

Our study results are similar to those reported in RCTs that have initiated PN within PCP settings, prior to receipt of a physicians’ referral, to CRCS nonadherent patients identified during scheduled PCP visits or related EMR/chart reviews.[25–27] These studies reported intervention effects ranging from 21% to 38% for PN, compared to 10% to 20% for usual care. Larger studies that have initiated PN within PCP settings after nonadherent patients received a physician’s referral for a specific CRCS test have achieved the highest post-intervention adherence rates (65% to 81%).[20–22] The relative differences between usual care, comparison and PN groups varied based on the components included in each type of intervention. Several studies have included interventions with multiple components (e.g., various combinations of mailed letters/educational materials/screening kits, telephone reminders, PN) or stepped increases in intervention components. PN, mailed materials or both typically yielded higher CRCS adherence rates than pure control or delayed intervention exposures. Significant differences between mailed materials and PN were generally not observed in these studies. This RCT is among the first to highlight the potential benefit of PN over mailed educational materials alone to increase CRCS.

Perhaps the most important contribution of the current study is its targeted focus on Latino Medicare enrollees living in the southwestern United States. Houston/Harris County, Texas is home to one of the largest concentrations of Latinos in the nation (41%, versus 17% in the U.S.), most of whom are Mexican-origin.[30] Latinos residing in the U.S., even those with

similar insurance coverage, are heterogeneous in terms of their lifestyles, health beliefs and health practices.[18,19,31,32] Many older Latinos in the Southwest may face system- and individual-level CRCS adherence barriers that differ not only from non-Latino Whites but also from Latinos residing in other U.S. regions. For example, some Latinos in the Southwest have reported traveling to Mexico or using alternative medicines because of their experiences with the U.S. healthcare system. In a study examining barriers to CRCS among Latinos living along the U.S.–Mexico border, Fernandez et al found that participants perceived the care they received in Mexico, compared to the U.S., as more efficient, comprehensive, humane and affordable.[33] Such perceptions are ideal targets for tailored PN aimed at addressing pervasive barriers to care that contribute to CRCS disparities.

Key barriers to CRCS adherence are lack of knowledge and awareness about CRCS and lack of a physician's recommendation.[7,10–12] Approximately half of participants reported at baseline that the main reason for their CRCS nonadherence was that they did not know or were not told by their physicians that they needed either a COL/FS or FOBT. There are several possible reasons for this finding. Older Latinos, like many Medicare enrollees in general, may face difficulties finding PCPs to coordinate their ongoing care[9,17] or receive most of their care from specialists who would not routinely discuss or provide CRCS referrals during patient visits. The problem may also stem from ineffective patient-provider interactions related to low health literacy, language/communication barriers, or biases and/or uncertainties known to be associated with reduced likelihood that providers will offer CRCS referrals.[34,35] Additionally, several studies have found that older Latinos and other minorities are more likely than non-Hispanic Whites to be clustered within PCPs who are generally less likely to recommend CRCS and other screenings.[11,35,36]

Consistent with historical trends observed from 2000 to 2010[5–7], we found that higher overall CRCS adherence rates were driven by increased uptake of COL/FS. Although USPSTF guidelines do not identify COL/FS as superior to FOBT, several PN studies conducted within the time frame of this study either focused on colonoscopy uptake as the only outcome of interest or found that PN was associated with higher use of FOBT that did not reach the level of statistical significance. These results are likely related to Medicare's coverage of screening colonoscopies for average-risk individuals beginning in 2001, which to some degree supplanted the demand for FOBT. Physician- or organizational-level bias toward endoscopic screening modalities may have also influenced higher uptake of colonoscopies. Some studies have reported patients' perceptions that colonoscopies are higher quality CRCS tests or that FOBTs are unsanitary or embarrassing drives CRCS preferences.[7,33] Among RCTs evaluating PN, notable exceptions are the studies by Green et al[22], which focused most PN efforts on facilitating CRCS using FOBT, and Myers et al[26], which first used baseline telephone surveys to identify patients' preferred CRCS test and then tailored stepped intervention approaches, with PN representing the highest level of intensity, to support each patient's choice rather than promoting a specific CRCS test. As CRCS technologies continue to be refined, specific PN services, alone or in combination with other patient support mechanisms, should be further evaluated as factors to help vulnerable patients identify and overcome barriers to uptake of their preferred screening methods.

Certain limitations must be considered when interpreting our results. Although the demonstration project was sufficiently powered to satisfy the project aims, our analytic sample was small relative to the overall demonstration project because we included only participants who were CRCS nonadherent at baseline according to USPSTF guidelines. A larger analytic sample would have produced more robust findings and allowed us to tease out associations between CRCS adherence and specific types of PN services delivered. Attrition in both study arms may have affected our ability to detect differences between groups for the specific outcomes reported here. The most common reason for participant attrition was commercial insurance companies' marketing campaigns that encouraged enrollees to switch from FFS to managed care. Increased managed care penetration may have also contributed to overall gains in CRCS adherence across groups. We relied on self-reported data collected at the termination of the demonstration project by interviewers not blinded to participants' group assignments. This procedure may have introduced reporting and/or recall bias and fails to precisely measure the time between PN initiation and CRCS adherence. Our findings differ from those previously reported,[28] which may be related to the above-referenced factors or other differences in analytical strategies that are unknown to us. Some PN participants may have received more or less intervention exposure, depending on their screening histories, because navigators were also tasked with increasing adherence with other screenings. Finally, our focus on Latino Medicare FFS enrollees in a single geographic area limits the generalizability of our findings. Despite these limitations, we fill a critical gap in the literature about Latino Medicare enrollees in a U.S. region with one of the largest and fastest growing Latino populations. The additional information gained about this population is a major strength of this study.

In conclusion, this is the first RCT, to our knowledge, to demonstrate that PN delivered outside of PCP settings is modestly effective in increasing CRCS adherence among Latino Medicare enrollees. Our findings, considered in context with existing literature, suggest that this strategy should be further evaluated as a complement to primary care-based PN and other care coordination initiatives for older Latinos. Future studies should explore the cost-effectiveness and comparative-effectiveness of integrating PN delivery across settings, including the evaluation of specific types of PN services and navigators associated with increased screening adherence and the optimal timing and location of services (such as community/senior centers, etc.) within the referral process.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Consolidated Standards of Reporting (CONSORT) Participant Flow Diagram

Note: CRCS indicates colorectal cancer screening; FOBT, fecal occult blood test; COL/FS, colonoscopy or flexible sigmoidoscopy.

*2 intervention and 2 control group participants were missing 6 month FOBT data.

FIGURE 2.

Self-Reported Reasons for CRC Nonadherence at Baseline, by Screening Method

CRC indicates colorectal cancer screening; FOBT, fecal occult blood test; COL/FS, colonoscopy or flexible sigmoidoscopy.

TABLE 1

Participant Characteristics by Study Group

Variable	All N=303 (%)	Comparison N=168 (%)	PN N=135 (%)	P- value
Age (years)				
50 to 64	75 (24.7)	38 (22.6)	37 (27.4)	0.34
65 to 75	228 (75.3)	130 (77.4)	98 (72.6)	
Gender				
Female	166 (54.8)	91 (54.2)	75 (55.6)	0.81
Male	137 (45.2)	77 (45.8)	60 (44.4)	
Primary language				
English only or English-Spanish	138 (45.5)	72 (42.9)	66 (48.9)	0.30
Spanish only	165 (54.5)	96 (57.1)	69 (51.1)	
Nativity status				
US-born	148 (48.8)	80 (47.6)	68 (50.4)	0.63
non US-born	155 (51.2)	88 (52.4)	67 (49.6)	
Relationship status				
Married or partnered	171 (56.4)	95 (56.6)	76 (56.3)	0.97
Not married, partnered	132 (43.6)	73 (43.4)	59 (43.7)	
Education ^a				
< HS diploma/GED	192 (64.7)	104 (63.4)	88 (66.2)	0.62
HS diploma/GED	105 (35.3)	60 (36.6)	45 (33.8)	
Access to USOC				
Yes	255 (84.2)	147 (87.5)	108 (80.0)	0.08
No	48 (15.8)	21 (12.5)	27 (20.0)	
SRH status				
Fair or poor	105 (34.7)	58 (34.5)	47 (34.8)	0.96
Good, very good, excellent	198 (65.3)	110 (65.5)	88 (65.2)	
Personal IBD diagnosis				
Yes	14 (4.6)	10 (6.0)	4 (3.0)	0.22
No	289 (95.4)	131 (94.0)	158 (97.0)	
Family CRC history				
Yes	19 (6.3)	12 (7.1)	7 (5.2)	0.49
No	284 (93.7)	156 (92.9)	128 (94.8)	

PN indicates patient navigation; SD, standard deviation; US, United States; HS, high school; GED, general education development; USOC, usual source of care provider; SRH, self-rated health; IBD = irritable bowel disease; CRC, colorectal cancer.

^aN=297 due to missing data.

TABLE 2

Association Between Patient Navigation and CRCS Adherence

	OR (95% CI)	P-value
CRCS adherence		
PN (unadjusted model) ^a	1.64 (1.02, 2.62)	0.04
PN (adjusted model) ^b	1.82 (1.11, 3.00)	0.02
-- 65 to 74 years (Ref: 50 to 64 years)	1.88 (1.01, 3.52)	0.05
-- Female (Ref: male)	0.99 (0.60, 1.65)	0.98
-- < HS diploma/GED (Ref: HS)	2.34 (1.36, 4.02)	<0.01
-- USOC (Ref: no USOC provider)	1.80 (0.87, 3.76)	0.12
FOBT		
PN (unadjusted model) ^a	1.57 (0.87, 2.81)	0.13
PN (adjusted model) ^b	1.79 (0.96, 3.33)	0.07
-- 65 to 74 years (Ref: 50 to 64 years)	2.18 (0.91, 5.26)	0.08
-- Female (Ref: male)	0.83 (0.44, 1.57)	0.56
-- < HS diploma/GED (Ref: HS)	2.72 (1.28, 5.76)	0.01
-- USOC (Ref: no USOC provider)	1.77 (0.68, 4.61)	0.24
COL/FS		
PN (unadjusted model) ^a	1.77 (1.07, 2.91)	0.03
PN (adjusted model) ^b	1.90 (1.13, 3.22)	0.02
-- 65 to 74 years (Ref: 50 to 64 years)	1.30 (0.68, 2.50)	0.43
-- Female (Ref: male)	1.54 (0.90, 2.67)	0.11
-- < HS diploma/GED (Ref: HS)	1.93 (1.08, 3.45)	0.03
-- USOC (Ref: no USOC provider)	1.62 (0.74, 3.58)	0.23

CRCS indicates colorectal cancer screening; OR, odds ratio; CI, confidence interval; PN, patient navigation; Ref, referent category; HS, high school; GED, general education development; USOC, usual source of care; FOBT, fecal occult blood test; COL/FS, colonoscopy or flexible sigmoidoscopy.

^aCRCS and COL/FS: N=303; FOBT, N=297.

^bAdjusted models included terms for age, gender, education and USOC provider status. CRCS and COL/FS: N=299; FOBT, N=293 because four participants were missing educational attainment data.