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Clinical Trial Participation among Ethnic/Racial Minority and Majority Patients with Advanced Cancer: What Factors Most Influence Enrollment?

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Abstract

Background: Studies using administrative data report that racial/ethnic minority patients enroll in clinical trials less frequently than white patients. We studied a cohort of terminally ill cancer patients to determine a) if racial/ethnic minority patients have lower rates of drug trial enrollment than white patients once socioeconomic characteristics are accounted for and b) what factors most influence drug trial enrollment among patients with advanced canceroverall.

***Methods*:** Coping with Cancer (CwC) is a National Cancer Institute/National Institute of Mental Health (NCI/NIMH)-funded multisite, prospective, longitudinal study of patients with advanced cancer. Baseline interviews assessed drug trial enrollment as well as socioeconomic characteristics. Logistic regression models estimated associations between drug trial enrollment and baseline characteristics. Stepwise, backward, and subset model selection was applied to select the final model where characteristics significant at $\alpha = 0.05$ remained in the model.

Results: At a median of 4.4 months prior to death, 35 of 358 patients (9.8%) were enrolled in a drug trial. In unadjusted analyses, race/ethnicity, health insurance, performance status, recruitment site, cancer type, preference for life-extending care, and lack of end-of-life care planning were associated ($p < 0.05$) with enrollment. In multivariable analysis, patient race/ethnicity was not significantly associated with enrollment. Patients who reported not having an end-of-life discussion (adjusted odds ratio [AOR], 0.18; 95% confidence interval [CI] 0.04–0.83) and those not wanting to discuss life expectancy (AOR, 0.31; 95%CI 0.12–0.79) were more likely to be trial enrollees.

Conclusion: Patient race/ethnicity was not associated with clinical trial enrollment after adjustment for socioeconomic covariates. Patients with advanced cancer endorsing less engagement in end-of-life planning were more likely to be enrolled in a clinical trial.

Introduction

Enrollment of American cancer patients in clinical trials has remained modest despite significant progress in cancer care as well as the federal government's own commitment to increasing participation over the past two decades.[1] Less than 5% of all adult cancer patients participate in a clinical trial.[2–4] Low rates of enrollment delay discovery of potentially life-sustaining therapies.

Of particular concern is the oft-cited underenrollment of racial and ethnic minorities. Rates of minority enrollment are conflicting. Some studies conclude that racial minorities enroll in clinical trials at a significantly lower rate than their nonminority counterparts[2,3]; others suggest that racial minorities

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enroll in clinical trials at rates that parallel their respective incidence of disease.[4]

These prior studies used large databases that provide little additional information about the patient's social or economic identity. The lack of such information is problematic given that psychosocial and economic factors may influence patient decision making, particularly when a patient has a limited life-expectancy.

Recent research on cancer care disparities supports this idea. Bhargava and Du[5] demonstrated that although black patients were less likely than their white counterparts to receive adjuvant chemotherapy for lymph-node-positive breast cancer at baseline, adjusted analyses that accounted for economic status attenuated the difference in care received. Similarly, Schwartz and colleagues[6] found that both access to care and socioeconomic status ameliorated initial disparities observed in the cancer care and cancer-specific survival between black and white prostate cancer patients. Analyses of hospice utilization between white and black patients have also demonstrated similar results.[7]

The primary objective of this study was to examine the association between the race/ethnicity of patients with advanced cancer and their participation in drug trials. We hypothesized that enrollment in a drug trial would not be associated with racial/ethnic affiliation when socioeconomic and psychosocial factors were taken into account. Our second aim was to determine the factors most associated with drug trial enrollment overall in this cohort of patients with advanced cancer.

Patients and Methods

Coping with Cancer (CwC) is a multisite study of patients with advanced cancer designed to examine the psychosocial attitudes, mental health, and health care preferences of a cohort of terminally ill cancer patients. Patients were recruited from seven outpatient cancer facilities between September of 2002 and August of 2008: Dana-Farber/Partners Cancer Center (Boston, MA), New Hampshire Oncology-Hematology (Londonderry, NH), Memorial Sloan-Kettering Cancer Center (New York, NY), Parkland Hospital (Parkland, TX), Simmons Comprehensive Cancer Center (University of Texas-Southwestern in Dallas, TX), West Haven Veterans Affairs Comprehensive Cancer Center, (West Haven, CT), and Yale Cancer Center (New Haven, CT). The institutional review board of each facility approved the study protocol.

A trained rater interviewed patients and caregivers individually in face-to-face encounters. Each rater received training in interview practices prior to initiation of the study and met preestablished criteria (e.g., kappa ratings of 0.90 or higher on psychiatric diagnoses between new and trained interviewers) before being permitted to conduct interviews for the study. All interviews were conducted in English or Spanish.

To meet criteria for inclusion, patients had to meet the following requirements. First, eligible patients must have had a diagnosis of either an advanced pulmonary, gastrointestinal, or brain cancer. These cancer types were selected to ensure inclusion of patients who, by virtue of tumor biology, would have a limited life expectancy. For the purposes of this study, advanced cancer was defined as either the presence of distant metastases or locoregional disease refractory to first-line chemotherapy. Other requirements for enrollment included: age greater than 20 years to ensure recruitment of an adult cancer population using the National Institutes of Health (NIH) definition of children as an individual age 20 years or below, the use of English or Spanish as the patient's primary language, and the absence of significant cognitive impairment (e.g., dementia, delirium) as determined by physician assessment at the time of the baseline screening interview. Medical staff and the interviewer determined whether at the time of enrollment the patient had adequate stamina to complete the interview. All participants signed written informed consent.

Of 1015 eligible patients, 726 (71.5%) enrolled. For the purposes of this study, only patients who were deceased at the time of study closure and had nonmissing data for clinical trial enrollment at baseline were included to ensure selection of patients with terminal disease. This final cohort of 358 patients did not differ significantly ($p < 0.05$) by cancer type, psychological distress, or rates of psychiatric disorders from the study participants at large. However, this cohort had a worse performance status, a higher symptom burden, and a lower baseline quality of life as would be expected in a cohort with shorter life expectancy. They were also more likely to be younger, female, uninsured, less educated, and to identify as a member of a racial or ethnic minority group.

Within the 358 patients included in this study, a subgroup sample with nonmissing data for the statistically significant confounders included in the multiple logistic regression analysis ($n = 325$) had significantly ($p < 0.05$) lower income and educational levels, was less likely to be married, less likely to have health insurance, less likely to be white or Jewish, and had worse performance status and higher symptom burden compared with the 33 patients not included in the final multiple regression analysis.

Primary outcome

Drug trial enrollment. Enrollment in a clinical trial was determined through chart review performed by a member of the patient's care team to answer the question, "Is the patient on a drug trial? If yes, what phase drug trial?"

Associations of interest

Patient race/ethnicity. As part of the patient interview, participants were asked: "What race or ethnicity do you consider yourself to be?" Responses were: "white," "black," "Asian-American, Pacific Islander or Indian," "Hispanic," "other," "refused," or "don't know."

Other covariates of interest

Patient factors that could also influence a patient's enrollment in a clinical trial were examined as potential confounders. These included:

Sociodemographic traits. These included patient's self-reported sex, age, religion, marital status, education, income, and health insurance coverage.

Recruitment site. The site was the location where the patient received treatment, for example, the Dana Farber Cancer Institute, Parkland Hospital.

Table 1. Associations of Baseline Characteristics with Clinical Trial Enrollment

Clinical Trial Experience					
Baseline characteristics	*Total (n=358)*	*Yes (n=35; 9.78%)*	*No (n=323; 90.2%)*	*OR (95% CI)*	P *value*
Race					
White	235 (66.01%)	29 (12.3%)	206 (87.7%)	2.70 (1.09–6.69)	0.032
Black	61 (17.13%)	2 (3.3%)	59 (96.7%)	0.27 (0.06–1.15)	0.077
Hispanic	53 (14.89%)	2 (3.8%)	51 (96.2%)	0.32 (0.08–1.38)	0.127
Asian	4 (1.12%)	2 (50.0%)	2 (50.0%)	9.67 (1.32–70.89)	0.026
Sociodemographics					
Age; mean (SD)	58.58 (12.66)	56.09 (11.59)	58.86 (12.76)	0.98 (0.96–1.01)	0.219
Male	194 (54.19%)	15 (7.73%)	179 (92.27%)	0.59 (0.29–1.20)	0.149
Family Income ≥$31,000	113 (31.56%)	11 (9.73%)	102 (90.27%)	1.62 (0.58–4.55)	0.362
Married	217 (60.61%)	24 (11.06%)	193 (88.94%)	1.41 (0.67–2.99)	0.365
Insured	220 (61.45%)	32 (14.55%)	188 (85.45%)	7.26 (2.18–24.22)	0.001
Education; mean (SD)	12.55 (4.09)	13.54 (3.58)	12.44 (4.14)	1.08 (0.98–1.18)	0.130
Religion					
Catholic	132 (36.87%)	16 (12.12%)	116 (87.88%)	1.49 (0.74–3.01)	0.267
Protestant	61 (17.04%)	3 (4.92%)	58 (95.08%)	0.43 (0.13–1.44)	0.168
Jewish	17 (4.75%)	5 (29.41%)	12 (70.59%)	4.29 (1.42–13.01)	0.010
Muslim	4 (1.12%)	1 (25.00%)	3 (75.00%)	3.12 (0.32–30.82)	0.330
No religion	16 (4.47%)	1 (6.25%)	15 (93.75%)	0.60 (0.08–4.68)	0.626
Pentecostal	9 (2.51%)	1 (11.11%)	8 (88.89%)	1.15 (0.14–9.48)	0.896
Baptist	53 (14.80%)	2 (3.77%)	51 (96.23%)	0.32 (0.07–1.38)	0.127
Recruitment site					
Yale Cancer Center	68 (18.99%)	21 (30.88%)	47 (69.12%)	8.78 (4.17–18.46)	0.000
Veterans Affairs CCC	12 (3.35%)	0 (0.00%)	12 (100.0%)	--------[a]	0.983
Simmons Center	34 (9.50%)	3 (8.82%)	31 (91.18%)	0.88 (0.25–3.04)	0.840
Parkland Hospital	141 (39.39%)	4 (2.84%)	137 (97.16%)	0.17 (0.06–0.51)	0.001
DFCI/MGH	8 (2.23%)	1 (12.50%)	7 (87.50%)	1.32 (0.16–11.08)	0.796
New Hampshire Heme/Onc	65 (18.2%)	2 (3.1)	63 (96.9)	0.25 (0.06–1.07)	0.061
Cancer type					
Lung	76 (21.23%)	3 (3.95%)	73 (96.05%)	0.32 (0.10–1.08)	0.066
Pancreatic	33 (9.22%)	9 (27.27%)	24 (72.73%)	4.31 (1.82–10.24)	0.001
Gallbladder	7 (1.96%)	0 (0.00%)	7 (100.0%)	--------[a]	0.987
Colon	45 (12.57%)	5 (11.11%)	40 (88.89%)	1.18 (0.43–3.21)	0.747
Brain	8 (2.23%)	2 (25.00%)	6 (75.00%)	3.20 (0.62–16.51)	0.164
Stomach	14 (3.91%)	1 (7.14%)	13 (92.86%)	0.70 (0.09–5.53)	0.737
Esophageal	12 (3.35%)	3 (25.00%)	9 (75.00%)	3.27 (0.84–12.70)	0.087
Performance status; mean (SD)					
Karnofsky Score	64.32 (16.54)	71.18 (18.05)	63.58 (16.23)	1.03 (1.01–1.06)	0.012
Zubrod Score	1.72 (0.91)	1.37 (0.94)	1.75 (0.9)	0.60 (0.39–0.92)	0.020
Charlson Index	8.34 (2.68)	7.03 (2.23)	8.48 (2.69)	0.80 (0.70–0.93)	0.003
McGill Quality of Life; mean (SD)					
Physical functioning	5.61 (2.66)	5.89 (1.99)	5.58 (2.72)	1.04 (0.91–1.20)	0.524
Symptoms	5.36 (2.13)	6.2 (1.6)	5.27 (2.17)	1.22 (1.04–1.44)	0.016
Psychological	7.22 (2.5)	7.46 (2.2)	7.2 (2.53)	1.04 (0.90–1.21)	0.563
Support	8.63 (1.67)	8.31 (1.44)	8.67 (1.69)	0.89 (0.74–1.08)	0.239
Summative score	6.79 (1.55)	6.98 (1.12)	6.76 (1.59)	1.10 (0.87–1.38)	0.431
Doctor-patient relationship					
How much trust your doctor; mean (SD) ($n=121$)	3.34 (1.20)	3.29 (1.50)	3.34 (1.19)	0.96 (0.52–1.78)	0.90
How much respect your doctor; mean (SD) ($n=121$)	3.45 (1.18)	3.29 (1.50)	3.46 (1.16)	0.89 (0.50–1.58)	0.70
Comfortable asking questions about your care ($n=329$)	0.89 (0.24)	0.87 (0.28)	0.89 (0.24)	0.74 (0.19–2.94)	0.67
EOL treatment preferences					
Extend life preference	83 (23.18%)	13 (15.66%)	70 (84.34%)	2.56 (1.15–5.71)	0.022
Against ICU death	121 (33.80%)	12 (9.92%)	109 (90.08%)	1.08 (0.51–2.32)	0.836
Prefer feeding tube	125 (34.92%)	10 (8.00%)	115 (92.00%)	0.76 (0.34–1.67)	0.491
Prefer ventilator	84 (23.46%)	8 (9.52%)	76 (90.48%)	1.04 (0.44–2.43)	0.930
Prefer chemotherapy	248 (69.27%)	27 (10.89%)	221 (89.11%)	4.28 (0.99–18.44)	0.051
Prefer antibiotics	199 (55.59%)	21 (10.55%)	178 (89.45%)	1.64 (0.70–3.82)	0.255

(*continued*)

Table 1. (Continued)

Clinical Trial Experience					
Baseline characteristics	*Total (n = 358)*	*Yes (n = 35; 9.78%)*	*No (n = 323; 90.2%)*	*OR (95% CI)*	P *value*
Advance care planning					
Terminal Illness acknowledgement	125 (34.92%)	9 (7.20%)	116 (92.80%)	0.62 (0.27–1.39)	0.243
End-of-life discussion	151 (42.18%)	6 (3.97%)	145 (96.03%)	0.25 (0.10–0.62)	0.003
Want doctor to tell life-expectancy	236 (65.92%)	16 (6.78%)	220 (93.22%)	0.39 (0.18–0.85)	0.017
Completed DNR order	138 (38.55%)	8 (5.80%)	130 (94.20%)	0.46 (0.20–1.06)	0.067
Had living will or DPA	181 (50.56%)	18 (9.94%)	163 (90.06%)	1.08 (0.51–2.28)	0.843

[a]Estimate could not be obtained.
DNR, do not resuscitate; DPA, durable power of attorney; EOL, end of life; ICU, intensive care unit; SD, standard deviation.

Cancer type. The cancer type was the tissue of origin, for example, lung, pancreas, gallbladder, colon, stomach, or esophagus.

Patient health. The patient's Karnofsky, Zubrod, and Charlson comorbidity index scores were documented by a member of the medical team. A high Karnofsky score implies a better performance status, whereas a low score on the Zubrod or Charlson comorbidity index reflects a higher performance status. The McGill Quality of Life Index was also administered by trained raters at the time of interview, where a high score implies a higher quality of life.[8–11]

Doctor-patient relationship. Patients were asked several questions about the relationship they had with their physician using The Human Connection Scale. Sample questions included: "How much do you trust your doctor?," "How much do you respect your doctor?," and "To what extent do you feel comfortable asking your doctor questions?" Answers were graded on a scale of 1 to 4, where a score of 1 corresponded to "Not at all" and a score of 4 corresponded to "A large extent."[12]

End-of-life treatment preferences. Patients were asked about the kind of medical care they would like to receive at the end of their life. For example: "If you could choose, would you prefer: 1) treatment that focused on extending life as much as possible, even if it meant more pain and discomfort, or 2) care that focused on relieving pain and discomfort as much as possible, even if that meant not living as long?" They were also asked specific yes/no questions including: "Would you want to be kept alive if it required being on a feeding tube?" or "Would you want to be kept alive if it required you being on a breathing machine?"

Advance care planning. Patients were asked a series of yes/no questions to ascertain their preferences for end-of-life care. These questions included: "Have you and your doctor discussed any particular wishes you have about the care you would want to receive if you were dying?," "If your doctor knew how long you had left to live, would you want him or her to tell you?," "Do you have a signed living will, or health care proxy, or durable power of attorney for health care?," and "Have you completed a do not resuscitate (DNR) order?"

Statistical analysis

*T*test, Cochran-Mantel-Haenszel test, and χ^2 test statistics were used, as appropriate, to test for significant differences between patients who did or did not report clinical trial enrollment at baseline. Multivariable logistic regression modeling was used to examine the association between clinical trial enrollment and the baseline patient characteristics that were significant in bivariate analyses. Stepwise, backward, and subset model selection procedures were applied to select the remaining significant confounders with an entry significance level of $\alpha = 0.2$ and a stay significance level of $\alpha = 0.1$. Only baseline characteristics significant at $\alpha = 0.05$ remained in the model. Factors that were significantly related both to race/ethnicity and to trial enrollment, and that rendered the effect of race/ethnicity on trial enrollment not statistically significant (i.e., $p > 0.05$) were considered confounders.

Statistical analyses were performed with SAS version 9.2 (SAS Institute, Cary, NC). We report two-tailed p values.

Results

Baseline patient characteristics: Univariate analysis

The cohort of patients with advanced cancer died a median of 4.4 months after the baseline assessment. Baseline characteristics are detailed in Table 1. In this study, 9.8% of patients ($n = 35$) were enrolled in a drug trial at some point during their cancer care, of which 8 patients (22.9%) were enrolled in a Phase I study, 9 patients (25.7%) were enrolled in a Phase II study, 7 patients (20%) were enrolled in a Phase III study, and the remaining 11 (31.4%) were not specified.

In univariate analysis, white or Asian race, Jewish religion, medical insurance, receiving care at Yale Cancer Center, primary pancreatic cancer, a better performance status, and fewer physical symptoms of illness were all significantly ($p < 0.05$) associated with clinical trial enrollment (Table 1). Patients who preferred life-extending care, those who did not want their doctor to tell them their life expectancy, and those who reported not having had an end-of-life discussion with their physician, were also more likely to be enrolled in a clinical trial at baseline (all $p < 0.05$).

Factors associated with clinical trial enrollment: Multivariable analysis

After adjustment for demographic and socioeconomic covariates including age, gender, marital status, insurance, and education, white race was not associated with clinical trial enrollment. Patients who reported that they did not have an end-of-life discussion with their physician (adjusted odds

Table 2. Adjusted Associations of Clinical Trial Enrollment with Baseline Predictors

	Clinical trial experience			*Adjusted result*	
Baseline correlate	*Total (n = 325)*	*Yes (n = 30, 9.2%)*	*No (n = 295, 90.8%)*	*OR/HR*	P *value*
End-of-Life discussion	67 (20.6)	2 (6.7)	118 (98.3)	0.18 (0.04–0.83)	0.03
Want doctor to tell life expectancy	70 (21.5)	16 (6.8)	219 (93.2)	0.31 (0.12–0.79)	0.01
Yale Cancer Center	120 (36.9)	21 (31.3)	46 (68.7)	12.26 (1.09–4.84)	< 0.0001
Lung cancer	235 (72.3)	3 (4.3)	67 (95.7)	0.17 (0.04–0.72)	0.02

Note: 325 patients had nonmissing data with the four baseline correlates.
HR, hazard ratio; OR, odds ratio.

ratio, [AOR] 0.18; 95% confidence interval [CI] 0.04–0.83; $p = 0.03$), those who did not want their doctor to tell them their life expectancy (AOR, 0.31; 95%CI 0.12–0.79; $p = 0.01$), and those treated at Yale Cancer Center were more likely to be enrolled in a clinical trial. Patients with a primary lung cancer were less likely to be enrolled in a clinical trial (Table 2). The remaining factors identified in the unadjusted analysis did not meet criteria ($p < 0.05$) for significance.

Confounders of the race/ethnicity effect on trial enrollment

Patient race/ethnicity was found to be statistically significant in predicting trial enrollment in the univariate analysis. Analyses were performed to test whether the other factors associated with clinical trial enrollment confounded the relationship between race and trial enrollment. The analyses compared patients who self-identified as "white" versus all other participants ("nonwhite") because the individual racial/ethnic groups did not have an adequate number of trial participants to yield reliable estimates. A confounding effect of white race on the likelihood of trial enrollment was observed for patient recruitment site (Yale Cancer Center, Parkland Hospital) and health insurance coverage (Table 3). Other factors including education, Jewish and Baptist religion, and pancreatic cancer were found to be partial confounders of trial enrollment.

Discussion

Consistent with prior studies of minority clinical trial enrollment, we found white patients were more likely to be enrolled in a clinical drug trial compared to nonwhite patients. Yet, in support of our hypothesis, when demographic and socioeconomic factors were accounted for, race did not remain a significant predictor of enrollment. Specifically, health insurance coverage and recruitment site proved confounders that explained the effect of race on clinical trial enrollment.

Although we are not the first to report the relationship between insurance status or location of care and clinical trial enrollment,[3,13–15] our analysis does support the association of each with minority race/ethnicity and serves to emphasize that the discrepancy in drug trial enrollment among racial/ethnic minorities may be one of access to care and not of cultural acceptance.[16] However, although the characteristics delineated above appear to mitigate the differences in clinical trial enrollment by patient race, it should not imply that bias, either explicit or implicit, does not exist or that there is no longer a need for clinical staff be vigilant about the need to enroll racial and ethnic minority cancer patients in clinic trials.

With respect to other factors that predicted clinical trial enrollment, patients with a primary lung cancer were significantly less likely to enroll in a clinical trial, whereas patients

Table 3. Associations between White Race and Clinical Trial Enrollment Controlling for Demographic and Psychosocial Characteristics

	No. of subjects	*AOR (95% CI)*[a]	P *value*
White race (base model)	356	2.70 (1.09–6.69)[b]	0.03
Plus age	356	3.15 (1.24–8.00)	0.02
Plus male	356	2.75 (1.11–6.83)	0.03
Plus health insured	**350**	**1.33 (0.50–3.58)**	**0.57**
Plus education	356	2.38 (0.89–6.41)	0.09
Plus Protestant religion	356	2.94 (1.18–7.33)	0.02
Plus Jewish religion	356	2.37 (0.94–5.97)	0.07
Plus Baptist religion	356	2.42 (0.97–6.06)	0.06
Plus Yale Cancer Center	**356**	**1.96 (0.76–5.07)**	**0.17**
Plus Parkland Hospital	**356**	**1.13 (0.40–3.22)**	**0.82**
Plus New Hampshire Heme/Onc	356	3.59 (1.44–9.00)	0.006
Plus Pancreatic cancer	356	2.30 (0.91–5.79)	0.08
Plus Brain cancer	356	2.62 (1.05–6.52)	0.04
Plus Lung cancer	356	2.78 (1.12–6.93)	0.03
Plus Esophageal cancer	356	2.72 (1.09–6.76)	0.03
Plus Karnofsky score	348	2.56 (1.02–6.41)	0.04
Plus Zubrod score	350	2.61 (1.05–6.50)	0.04
Plus Charlson Index	355	2.96 (1.19–7.41)	0.02
Plus End-of-life discussion	355	3.18 (1.27–7.97)	0.01
Plus want doctor to tell life-expectancy	325	3.33 (1.22–9.05)	0.02
Plus general self-efficacy	317	2.94 (1.09–7.95)	0.03
Plus extend life preference	289	3.02 (1.08–8.40)	0.03
Plus prefer chemotherapy	319	3.26 (1.20–8.83)	0.02
Plus completed DNR order	322	3.73 (1.37–10.19)	0.01
Plus McGill symptoms	354	2.99 (1.19–7.50)	0.02

[a]The adjusted ORs account for demographic and psychosocial variables.
[b]The OR for the base model is unadjusted.
Sample sizes vary due to missing data.
AOR, adjusted odds ratio; CI, confidence interval; DNR, do not resuscitate.
Bold indicates no statistical significance.

treated at the Yale Cancer Center, those not reporting having had an end-of-life discussion with one's physician, and those not wanting a physician to relay one's life expectancy were all positively associated with clinical trial participation. It is unclear why patients with lung cancer were less likely to enroll in a trial compared with the cohort at-large, although other logistical factors historically thought to impact trial enrollment and not captured by our study, including physician preference, trial availability, or distance from a participating trial center could have played a role.[3] In reference to the association between Yale Cancer Center and trial enrollment, as mentioned in a prior report,[17] this site appeared to treat all our enrolled patients more aggressively compared with other participating sites, with both higher rates of aggressive care and lower utilization of hospice care than other participating medical centers.

Of particular interest was the finding that all patients who had enrolled in a drug trial were significantly less likely to report having had an end-of-life discussion with their doctor and were also significantly less likely to want to know their life expectancy from their physician even after controlling for numerous potential confounders (Table 1). As all responses in our study relied on patient recall, we cannot know if end-of-life care conversations were never held between patients and their doctors or if patients simply did not remember such discussions. Yet, this is the first study that we know of to find a significant association between clinical trial enrollment and patient lack of interest in life expectancy and reporting of end-of-life discussions. This association does suggest an interaction between terminal illness engagement and the receipt of experimental medical care.

Previously published research about end-of-life care has shown that patients who do not report an end-of-life discussion with their physician are more likely to receive aggressive, costly medical care, and both aggressive care and higher health care costs are associated with a worse quality of death.[17–19] Racial minorities in particular are more likely to present with advanced disease and more likely to receive aggressive end-of-life care.[18,20] In light of the results of this report, it appears that both minority and majority ethnic status terminally ill patients who participate in clinical trials are likely to benefit from counseling regarding end-of-life care planning.

There are several limitations to this study. First, our study is limited by the modest number of patients who participated in a clinical trial. Consequently, we may have failed to detect some factors that are associated with trial enrollment that might emerge in larger samples. Second, our trial was restricted to patients who spoke either English or Spanish as their primary language. Patients belonging to racial or ethnic groups where a language other than English or Spanish is primarily spoken would have been excluded from our study and therefore, we can draw limited conclusions regarding clinical trial enrollment rates in these populations. Furthermore, the design of this trial did not permit the coding of ethnicity as a separate variable from race. Hence, this could have resulted in the grouping of a subset of patients with Hispanic ethnicity into a different category, for example, white or black. However, as patients were asked to self-identify using a list of choices, they were free to select the option with which they most identified. Therefore, we believe that the potential impact of this choice is unlikely to be profound.

Finally, whereas our study attempted to delineate some of the psychosocial factors that could influence trial enrollment in a cohort of patients with advanced cancer, a multitude of factors remain that could not be addressed within this analysis. For example, this study lacked information regarding patients' eligibility for, or knowledge of, available clinical trials. Therefore, we can draw no conclusions about the reasons why the participants in our study were or were not enrolled in a trial. We also have no information regarding a patient's enrollment in a nondrug trial as all patients were only screened for participation in a drug trial. Additionally, the timing of patient's trial enrollment and their diagnosis of advanced cancer is unknown, so some patients may have enrolled in a clinical trial before they were considered to have advanced disease, or after our baseline assessment, and these data were not captured in the present analysis.

Despite these limitations, our study demonstrates that patients with advanced cancer self-identifying as Asian, black, or Hispanic are equally likely to enroll in a clinical trial as their white counterparts when socioeconomic and clinical factors are taken into account. Additionally, patients with advanced cancer who do enroll in drug trials are less likely to report an end-of-life care discussion or to want to know their life expectancy than patients with no history of drug trial participation. Additional research is required to explore further nuances of the doctor-patient interaction as it relates to end-of-life care discussions and clinical trial decision making. In the interim, this study suggests a tension between advance care planning and drug trial participation. It also underscores the importance of end-of-life care planning for patients participating in clinical trials.

Author Disclosure Statement

No competing financial interests exist.

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