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Determinants of Loss to Follow-Up in a Socio-Demographically Diverse Cohort of Prostate

Cancer Patients.

By

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Epidemiology

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Determinants of Loss to Follow-Up in a Socio-Demographically Diverse Cohort of Prostate Cancer Patients.

By

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An abstract of A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Epidemiology 2023

Abstract

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Determinants of Loss to Follow-Up in a Socio-Demographically Diverse Cohort of Prostate Cancer Patients. By Ajay Kumar Panda

Background: Research on patients living with prostate cancer is typically done through prospective longitudinal cohort studies. Analyses investigating the magnitude and sources of loss of follow up improve understanding the role of selection bias in this type of studies. . **Methods:** African-American and Non-Hispanic White males \leq 75 years of age newly diagnosed with low risk prostate cancer were identified in metro-Detroit and State of Georgia population-based cancer registries. The participants were asked to complete baseline, 2-year, and 5-year follow-up surveys. Log-binomial models were used to examine the associations between various sociodemographic factors and loss to follow up with results expressed as risk ratios (RR) and 95% confidence intervals (CI)

Results: Among 1687 study participants, 1161 (68.8%) completed at least one follow up survey, and of those 714 (61.5%) completed all of the surveys. The most consistent factor inversely associated with study drop out was income. Compared to men with annual income of <\$30,000 the RR (95% CI) estimates among those reporting income of >\$90,000 were 0.63 (CI:0.49-0.81) for any loss to follow and 0.75 (0.59-0.96) for incomplete follow up. Loss of follow up was also less likely in metro Detroit than in the State of Georgia. In the analyses stratified by race, African Americans were significantly less likely (RR=0.65; 95% CI: 0.47-0.89) to have incomplete follow up, if their first course of treatment included tumor directed therapy (surgery or radiation) versus conservative approach (active surveillance or watchful waiting. By contrast, among Non-Hispanic Whites the same association was in the opposite direction (RR=1.33; 95% CI: 1.12-1.58).

Conclusions: These results show that methods of preventing drop out may need to be customized to different population subgroups, especially persons of lower SES. These observations merit future studies with the focus on comparative effectiveness of various interventions aimed at preventing loss of follow up in cohort studies of prostate cancer patients.

Cover Page

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INTRODUCTION

Selection bias is defined as "a distortion in a measure of association (such as a risk ratio) due to a sample selection that does not accurately reflect the target population".¹ This type of bias threatens the internal validity of a study, which in turn, also puts the external validity in jeopardy. Moreover, among persons excluded from the study due to selection bias, the exposure-outcome association is unknown so the true direction and magnitude of selection bias can be hard to predict or quantify.²

The sources of selection bias depend on the study design. In a prospective cohort study, the main source of selection bias is differential loss to follow-up.^{2,3} It is generally expected that a drop out of 5% or less provides sufficient reassurance that the bias, if any, will have minimal impact whereas greater than 20% attrition may signal bias of considerable magnitude.³ On the other hand, studies have reported that a loss of follow up as high as 30% had minimal influence on the measured associations.⁴

The prospective longitudinal study design is most suitable when investigating risk factors or assessing long-term treatment outcomes of chronic diseases.^{5,6} A classic example of this type of design is the Framingham Heart Study that was established in 1948 and followed residents of a neighborhood near Boston, Massachusetts for three generations. Through the past few decades this study has found key information about both non-modifiable and modifiable risk factors for cardiovascular disease.⁷ These findings have helped shaped the way modern physicians provide care and treatment for patients who are at risk for heart disease today. Another example is a cohort of people residing in Gothenburg, Sweden; a study of stroke risk factors that utilized a

44-year, multigenerational follow up.⁸ This study showed that aside from the classical stroke risk factors such as hypertension, atrial fibrillation, diabetes, etc.; vulnerability factors such as low education and poor oral health are also independently related to stroke risk. ⁸ The authors of this study, however, noted that although their study has strong levels of participation, this might have been due to a small study population which can limit generalizability. ⁸ Both these studies show that much can be learned about chronic disease through examining them with the lens of a longitudinal cohort study.

Prostate cancer outcomes research often relies on a longitudinal prospective cohort study design. This is likely because randomization to different types of prostate cancer treatments may be difficult and follow up after diagnosis may need to extend to a decade or more.

A widely referenced cohort of this type is the Prostate Cancer Outcomes Study (PCOS) which aimed to understand health-related quality of life measure in men living with prostate cancer.⁹ At the start of this study many of the literature regarding prostate cancer, relied on smaller, unique sample sizes which missed on the longer-term health quality effects of cancer patients.^{10–} ¹³ The PCOS study was designed to address these limitations by surveying 5672 men newly diagnosed with prostate cancer across six different SEER cancer registries from 1995 to 1999 and follow the participants up to 15 years after diagnosis.⁹

Another example of a prospective cohort of prostate cancer patients is the still on-going Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study, which recruited over 3600 men diagnosed with prostate cancer in 2010-2012 with the plan to follow them for at least 10 years.¹⁴ CEASAR reported a 50% initial response and a 86% follow-up completion after 12-months.⁶

As prostate cancer does not have a single agreed-upon management protocol selection of optimal prostate cancer treatment modality is an important area of ongoing research Of particular interest is the examination of factors that may influence a decision to opt for active surveillance in patients with lower risk disease.¹⁵ Active surveillance is a structured management program that includes monitoring blood levels of prostate specific antigen (PSA) along with repeated biopsies to track the disease progression while delaying or deferring a definitive tumor-directed therapy such as radical prostatectomy of radiation.¹⁵ Active surveillance is endorsed by the American Society of Clinical Oncology for most men with high life expectancy and low-risk localized prostate cancer.¹⁶ Another conservative approach to prostate cancer management is watchful waiting, which does not involve serial biopsies or PSA testing and is typically reserved for men with low life expectancy.¹⁷

Treatment Options of Prostate Cancer Study (TOPCS); is an ongoing prospective cohort with specific focus on men who selected conservative approach (active surveillance or watchful waiting) as their treatment of choice.¹⁸ This study was designed to include Non-Hispanic white and African-American men newly diagnosed with prostate at two locations – the Detroit Metropolitan Area in Michigan and the State of Georgia. During the study, participants were surveyed at baseline, and two and five years of follow up. As the study sought to recruit participants from hard-to-reach population groups, including African American men and rural residents, it is important to assess if losses to follow up differed across different categories of

cohort members. With these considerations in mind, the goal of this paper is to examine factors associated with to loss of follow-up among TOPCS participants.

METHODS

Data Collection

The details of TOPCS research protocol were reported previously elsewhere.¹⁸ Candidates for inclusion in the TOPCS cohort were 4,775 low-risk prostate cancer patients reported to the Surveillance Epidemiology and End Results (SEER) registries in Metro Detroit and the State of Georgia Of those 3,871 were selected to receive a baseline survey based on eligibility criteria and 1,687 participants completed and returned the baseline survey packets. Participants who completed the baseline surveys were contacted again 2-years and 5-years after initial recruitment to monitor their experiences with active surveillance or tumor-directed treatment they received.

Variables

The baseline study surveys collected socio-demographic data on race (Non-Hispanic White or African American), age, education, and income. The age variable was divided into five groups: under 60, 61-64, 65-70, 71-74, and older than 75 years. Education was categorized as high school or less, at least some college, graduate, and unknown/refused to report. The annual income was classified into five categories: under \$30,000, \$31,000-\$50,000, \$51,000-\$90,000, and greater than \$90,000. Each study participant was further characterized with respect to his initial treatment as receiving conservative management (including both active surveillance and watchful waiting) or tumor-directed therapy (prostatectomy or radiation). The main outcome of interest, loss to follow up, was expressed using two approaches. The first approach (no vs. any follow up) compared participants who completed only the baseline survey to those who returned at least one follow up questionnaire. The second approach (incomplete vs. complete follow up)

sub-divided the "any follow-up" group into two categories: those who completed only one of the two surveys versus those who responded to both follow up surveys .

Statistical Analysis

The associations of independent variables of interest (age, race, study site, income, education, and initial treatment) with the risk of loss to follow up were examined using multivariable log binomial models. Separate models were constructed for the any vs. no follow up and for the complete vs. incomplete follow up. The results of all models were expressed as risk ratios (RR) and the corresponding 95% confidence intervals (CI). All models were examined for collinearity and for two-way interactions between race and each of the covariates. In the presence of statistically significant interactions the data were further analyzed using race-specific models. All data analyses were conducted using SAS, version 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

Table 1 displays the socio-demographic characteristics of study participants by "any follow up" status. Among 1687 participants who responded to the baseline questionnaire, 1161 (68.8%) completed at least one of the follow up surveys. Men who completed at least one follow up survey represented approximately 70% of participants residing in the Detroit area, compared to 66% of Georgia participants. A greater proportion of follow up survey respondents was observed among Non-Hispanic Whites (71%) and participants under 60 years of age (70%), versus African-Americans (59%), and older men, especially those over the age of 75 years (58%). As level of education and annual household income increased, so did the probability of completing at least one survey. Among men with income <\$30,000 and those with no more than high school education, only 58% and 53% persons, respectively, provided any follow up data. By contrast, among those with annual income over \$90,000 and those with a graduate degree the corresponding proportions were 79% and 77%.

As shown in **Table 2**, among 1161 participants in the "any follow up" group, 714 (61.5%) completed all surveys. The differences between the "complete follow up" and the "incomplete follow up" groups were similar to those observed when comparing men who completed only baseline survey to those who completed at least one follow up survey. Respondents who completed all surveys were over-represented among participants residing in Detroit compared to Georgia (66% vs. 55%), Non-Hispanic Whites compared to African Americans (62% vs. 58%) and men in the youngest compared to the oldest age group (58% vs. 50%). Similarly, the likelihood of completing all surveys increased with increasing annual household income and

higher levels of education; from 53% to 64% in the lowest and highest income categories and from 55% to 65% in the lowest and highest education categories, respectively.

Table 3 shows the results of the log binomial models that included all variables listed in Tables 1-2 and analyzed two binary outcome measures: "no follow up vs. any follow up" and "incomplete vs. complete follow up". After controlling for covariates, only study site and income were independently associated with lower risk of dropout in both analyses. Compared to participants from Georgia those residing in Detroit had 28% lower risk (95% CI: 0.70-0.96) for no vs any follow up and 20% lower risk (95% CI: 0.69-0.93) for incomplete vs. complete follow up. The corresponding RR (95% CI) estimates comparing person in the highest (at least \$90,000) to the lowest (\$30,000 or lower) annual household income categories were 0.63 (0.49-0.810 and 0.75 (0.59-0.96). The association with education was also statistically significant (RR=0.64; 95% CI: 0.51-0.81), but only in the analyses that defined the outcome measure as no follow up vs. any follow up. All other RR estimates in the two models were not significantly different from the null value.

Some of the two-way interactions between race and other covariates in the model were statistically significant. For this reason, we re-analyzed the data separately for African American men and Non-Hispanic Whites (**Table 4**). The race-specific results were generally similar to those observed in the overall model, but with two notable exceptions. First, the previously observed association between study site and risk of dropout was only evident among Non-Hispanic Whites, but not African-Americans. Second, among African-Americans, men who received tumor-directed prostate cancer treatment (surgery or radiation) were more likely to drop out of the study compared to men who opted for conservative approach (active surveillance or watchful waiting), whereas the same association was in the opposite direction among Non-Hispanic Whites. This difference was especially pronounced, with non-overlapping confidence intervals (0.47-0.98 vs 1.12-1.58) in the model that used incomplete vs. complete follow up as the dependent variable of interest.

DISCUSSION

This analysis of losses to follow-up in a geographically, demographically and socioeconomically diverse cohort of prostate cancer patients produced several notable observations. The two factors consistently found to be related to failure to initiate and complete follow up included lower annual income and residence in Georgia. These factors remained independently associated with the loss to follow up after controlling for other variables. Whereas race appeared to be related to loss to follow up in crude analyses, this association was no longer evident after the results were adjusted for other sociodemographic characteristics. Interestingly, treatment type was not significantly associated with the outcomes of interest until the data were stratified by race. Following stratification, however, African Americans were 35% less likely to have incomplete follow up, if their first course of treatment included tumor directed therapy (surgery or radiation) versus conservative approach (active surveillance or watchful waiting). By contrast, among Non-Hispanic Whites the same association was in the opposite direction; men who received tumor directed therapy were 33% more likely to have incomplete follow up relative to their counterparts who elected to start active surveillance or watchful waiting.

While our literature search identified no analogous studies of losses to follow up among participants in prostate cancer research, useful data are available from similarly designed studies conducted in clinical settings. Ginsburg and co-authors examined rates of loss to follow-up in a large cohort of prostate cancer patients undergoing active surveillance across 44 academic and community urology practices in the state of Michigan.¹⁹ The authors reported a two-year loss to follow up of approximately 10%. The risk of drop out was especially high in African American men and patients described as "generally unhealthy". After adjusting for age, clinical prostate

cancer characteristics and comorbidities, the two-year risk of loss to follow up ranged between 1% and 48%, depending on the individual practice. These findings, as well as findings from studies conducted for other cancers as well as certain communicable diseases,^{20,21} indicate that loss to follow up constitutes an important problem not only in research, but also in clinical practice, and highlight the importance to sociodemographic characteristics as determinants of patient drop out.

By focusing on losses to follow up in a cohort of low risk prostate cancer patients eligible for active surveillance, the present study offers an interesting perspective on a rather unique study population. In addition, by including Black and White patients from Michigan and Georgia the data allowed evaluating the independent roles of race, geographic location and socio-economic characteristics as determinants of losses of follow up. Moreover, by conducting separate analyses by race we were able to identify the differential impact of various determinants of cohort attrition in Non-Hispanic White and African-American men.

The marked racial discrepancy in the association between initial treatment choice and loss to follow up is difficult to explain. The inability to interpret this interesting finding highlights the important limitation of the present study – a lack of data on the specific patient-reported reasons for study drop out. Obtaining such information likely requires a separate mixed methods study involving additional collection of both quantitative and qualitative data on factors that precipitated failure to respond to follow up surveys. Whether or not such study is feasible, however, remains debatable since losses to follow by definition occur when the cohort members actively refuse to participate or when methods of contacting study participants are exhausted. It

is important to point out, however, that active refusal represented a very small proportions of losses to follow up in our study. An additional limitation of the present study is the relatively unbalanced representation of large metropolitan versus small urban or rural areas. Whereas the Michigan site was confined to the Metro-Detroit area, the Georgia site included the entire state. An inclusion of statewide data from both sites would have improved our ability to compare cohort attrition by level of urbanization. Further, with the follow up limited to 5 years, our data may be less robust than similar data in other population-based cohorts of prostate cancer patients that followed their participants for a total of 10 to 15 years.^{6,9}

These limitations notwithstanding, the results of the present study show that the methods of preventing cohort attrition may need to be customized to different population subgroups, especially persons of lower socioeconomic status. These observations merit future research with the focus on comparative effectiveness of various interventions aimed at preventing loss to follow up in cohort studies of prostate cancer patients. In addition, the results of this study may inform re-analyses of the available data with the use of inverse selection probability weighted models aimed at correcting biases resulting from differential losses to follow up.

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TABLES

Table 1.	Descriptive	characteristics	of study	participant	s bv anv	follow up status

Participant characteristics	Enrolled		Completed	<u>baseline only</u>	Completed any follow up	
Farticipant characteristics	Ν	%*	Ν	%**	Ν	%**
Age (years)						
≤60	624	37.0	187	30.0	437	70.0
61-64	329	19.5	97	29.5	232	70.5
65-70	498	29.5	169	33.9	329	66.1
71-74	205	12.2	60	29.3	145	70.7
75+	31	1.8	13	41.9	18	58.1
Study site						
Metro Detroit area	925	54.8	268	29.0	657	71.0
State of Georgia	762	45.2	258	33.9	504	66.1
Race/ethnicity						
Non-Hispanic Whites	1340	79.4	385	28.7	955	71.3
African Americans	347	20.6	141	40.6	206	59.4
Education						
High school or less	306	18.1	145	47.4	161	52.6
Some college	564	33.4	174	30.9	390	69.1
Graduate	781	46.3	178	22.8	603	77.2
Unknown/Refuse	36	2.1	29	80.6	7	19.4
Household Income						
≤\$30,000	243	14.4	103	42.4	140	57.6
\$31,000-\$50,000	263	15.6	105	39.9	158	60.1
\$51,000-\$90,000	386	22.9	119	30.8	267	69.2
\$90,000+	654	38.8	137	20.9	517	79.1
Unknown/Refuse	141	8.4	62	44.0	79	56.0
Initial treatment						
Tumor-directed therapy	624	37.0	206	33.0	418	67.0
Conservative management§	1048	62.1	315	30.1	733	69.9
Total**	1687	100.0	526	31.2	1161	68.8

* Column percentages ** Row percentages § Includes active surveillance and watchful waiting

Doution on the statistics	Completed a	ny follow up	Incomplet	te follow u <u>p</u>	Completed entire follow up	
Participant characteristics	Ν	%	Ν	%**	Ν	0⁄0**
Age (years)						
≤60	437	37.6	184	42.1	253	57.9
61-64	232	20.0	77	33.2	155	66.8
65-70	329	28.3	124	37.7	205	62.3
71-74	145	12.5	53	36.6	92	63.4
75+	18	1.6	9	50.0	9	50.0
Study site						
Metro Detroit area	657	56.6	221	33.6	436	66.4
State of Georgia	504	43.4	226	44.8	278	55.2
Race/ethnicity						
Non-Hispanic Whites	955	82.3	360	37.7	595	62.3
African Americans	206	17.7	87	42.2	119	57.8
Education						
High school or less	161	13.9	72	44.7	89	55.3
Some college	390	33.6	159	40.8	232	59.5
Graduate	603	51.9	213	35.3	390	64.7
Unknown/Refuse	7	0.6	4	57.1	3	42.9
Household Income						
≤\$30,000	140	12.1	66	47.1	74	52.9
\$31,000-\$50,000	158	13.6	74	46.8	84	53.2
\$51,000-\$90,000	267	23.0	97	36.3	170	63.7
\$90,000+	517	44.5	186	36.0	331	64.0
Unknown/Refuse	79	6.8	23	29.1	55	69.6
Initial treatment						
Tumor-directed therapy	418	36.0	176	42.1	242	57.9
Conservative management§	733	63.1	266	36.3	467	63.7
Total**	1161	100.0	447	38.5	714	61.5

Table 2. Descriptive characteristics of study participants who had any follow up by follow up completion status

* Column percentages ** Row percentages § Includes active surveillance and watchful waiting

Doution and about staristics	<u>No vs</u>	<u>. any follow up.</u>	Incomplete vs. complete follow up		
Participant characteristics	RR	95% CI	RR	95% CI	
Age (years)					
≤60	1.0	(reference)	1.0	(reference)	
61-64	1.01	0.94-1.08	0.95	0.88-1.01	
65-70	1.02	0.89-1.17	0.90	0.78-1.03	
71-74	1.03	0.83-1.26	0.85	0.69-1.05	
75+	1.04	0.79-1.38	0.81	0.61-1.07	
Study site					
State of Georgia	1.0	(reference)	1.0	(reference)	
Metro Detroit area	0.82	0.70-0.96	0.80	0.69-0.93	
Race/ethnicity					
African Americans	1.0	(reference)	1.0	(reference)	
Non-Hispanic Whites	0.95	0.79-1.14	1.03	0.85-1.25	
Education					
High school or less	1.0	(reference)	1.0	(reference)	
Some college	0.80	0.71-0.90	0.96	0.86-1.08	
Graduate	0.64	0.51-0.81	0.93	0.74-1.16	
Household Income					
≤\$30,000	1.0	(reference)	1.0	(reference)	
\$31,000-\$50,000	0.86	0.79-0.93	0.91	0.84-0.98	
\$51,000-\$90,000	0.74	0.62-0.86	0.83	0.71-0.97	
\$90,000+	0.63	0.49-0.81	0.75	0.59-0.96	
Initial treatment					
Conservative management**	1.0	(reference)	1.0	(reference)	
Tumor-directed therapy	1.02	0.87-1.20	1.13	0.96-1.31	

Table 3. Multivariable analyses* of the factors associated with study drop out

* Column percentages ** Row percentages § Includes active surveillance and watchful waiting

Participant characteristics	<u>No vs. any follow up</u> (African-Americans)		<u>No vs. any follow up</u> (Non-Hispanic Whites)		<u>Incomplete vs. complete follow</u> <u>up (African-Americans)</u>		Incomplete vs. complete follow up (Non-Hispanic Whites)	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Age (years)								
≤60	1.0	(reference)	1.0	(reference)	1.0	(reference)	1.0	(reference)
61-64	1.02	0.89-1.17	0.99	0.91-1.07	0.95	0.80-1.11	0.95	0.88-1.02
65-70	1.03	0.77-1.36	0.99	0.84-1.15	0.89	0.64-1.23	0.9	0.77-1.05
71-74	1.05	0.70-1.36	0.98	0.77-1.23	0.84	0.51-1.38	0.86	0.68-1.08
75+	1.07	0.62-1.85	0.97	0.71-1.32	0.80	0.41-1.54	0.81	0.59-1.11
Study site								
State of Georgia	1.0	(reference)	1.0	(reference)	1.0	(reference)	1.0	(reference)
Metro Detroit area	1.11	0.83-1.48	0.73	0.61-0.88	0.92	0.68-1.25	0.77	0.65-0.91
Education								
High school or less	1.0	(reference)	1.0	(reference)	1.0	(reference)	1.0	(reference)
Some college	0.79	0.64-0.98	0.81	0.71-0.93	0.85	0.67-1.09	0.99	0.87-1.14
Graduate	0.63	0.41-0.96	0.66	0.51-0.86	0.73	0.44-1.19	0.99	0.77-1.30
Household Income								
≤\$30,000	1.0	(reference)	1.0	(reference)	1.0	(reference)	1.0	(reference)
\$31,000-\$50,000	0.99	0.86-1.14	0.82	0.75-0.90	0.87	0.75-1.01	0.93	0.84-1.02
\$51,000-\$90,000	0.99	0.74-1.31	0.67	0.56-0.81	0.75	0.55-1.02	0.86	0.71-1.05
\$90,000+	0.98	0.65-1.50	0.55	0.42-0.73	0.65	0.41-1.03	0.80	0.60-1.07
Initial treatment								
Conservative management**	1.0	(reference)	1.0	(reference)	1.0	(reference)	1.0	(reference)
Tumor-directed therapy	0.76	0.56-1.04	1.16	0.97-1.39	0.65	0.47-0.89	1.33	1.12-1.58

Table 4. Multivariable analyses* of the factors associated with failure to obtain any follow up data among those who completed baseline surveys, stratified by race/ethnicity

* Performed using log-binomial models that include all variables listed in the table, all missing values were excluded **includes active surveillance and watchful waiting