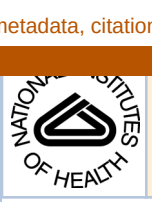

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Determinants of Medical System Delay in the Diagnosis of Colorectal Cancer within the Veteran Affairs Health System

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Abstract

Background & Aims—The goals of this study were to evaluate determinants of the time in the medical system until a colorectal cancer diagnosis and to explore characteristics associated with stage at diagnosis.

Methods—We examined medical records and survey data for 468 patients with colorectal cancer at 15 Veterans Affairs medical centers. Patients were classified as screen-detected, bleeding-detected, or other (resulting from the evaluation of another medical concern). Patients who

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presented emergently with obstruction or perforation were excluded. We used Cox proportional hazards models to determine predictors of time in the medical system until diagnosis. Logistic regression models were used to determine predictors of stage at diagnosis.

Results—We excluded 21 subjects who presented emergently leaving 447 subjects; the mean age was 67 years and 98% were male, 66% Caucasian, and 43% stage I or II. Diagnosis was by screening for 39%, bleeding symptoms for 27% and other for 34%. The median times to diagnosis were 73–91 days and not significantly different by diagnostic category. In the multivariable model for time-to-diagnosis, older age, having comorbidities, and Atlantic region were associated with a longer time to diagnosis. In the multivariable model for stage-at-diagnosis only diagnostic category was associated with stage; screen-detected category was associated with decreased risk of late stage cancer.

Conclusions—Our results point to several factors associated with a longer time from the initial clinical event until diagnosis. This increased time in the health care system did not clearly translate into more advanced disease at diagnosis.

Introduction

Colorectal cancer (CRC) remains a large public health burden. In the United States, CRC is the third most commonly diagnosed cancer [1]. When diagnosed at an early, localized stage, the 5-year survival rate reaches 90%. In contrast, patients presenting with distant metastases have a 5-year survival rate of only 10% [1].

A diagnosis of CRC may be the result of screening asymptomatic patients or from the evaluation of symptoms or abnormal tests. Delay in making a diagnosis has often been divided into patient delay: the delay in the patient visiting a clinician for symptoms and system delay: the delay providers and medical systems to fully evaluate symptoms or abnormal tests. Diagnostic delay is important because it could be related to poorer patient outcomes.

Study results have been inconsistent regarding the impact of delays in diagnosing CRC on stage or survival. In a systematic review, 20 of 26 studies found no association between time to diagnosis and survival, four studies found improved survival with increased time to diagnosis, and two studies found lower survival with increased time to diagnosis [2]. A recent study performed at a single Veterans Affairs (VA) facility found that a longer time from colonoscopy referral to endoscopic diagnosis of CRC was associated with a less advanced cancer stage and decreased mortality [3]. A retrospective review of 733 symptomatic patients with CRC in Denmark found that a delay of >60 days was significantly associated with more advanced stage at diagnosis [4].

Other potential outcomes of delay could include decreased patient satisfaction, increased patient worry, and inefficient or wasteful use of medical services if inappropriate tests are ordered. Research evidence to support these possibilities is lacking, but concern for them is reflected in policies to reduce medical system delay. For example, the VA has a goal of 60 days from a positive fecal occult blood test (FOBT) until colonoscopy and collects data on the proportion of patients meeting this goal as part of ongoing quality assessment. While consideration of a goal to reduce delay is reasonable, evidence from multicenter VA studies to support or refute the specific targets is lacking. Colonoscopy is a limited resource in the VA system therefore policies that impact use should be evidence-based.

We designed a study combining data from a multicenter observational study in the VA system with additional medical record abstraction to determine predictors of medical system

delay and to evaluate characteristics associated with stage at diagnosis, including time to diagnosis.

Methods

Setting and Sample

The Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) is a large observational study examining treatment and outcomes for patients with colorectal and lung cancer [5]. CanCORS is a collaboration of seven teams of investigators in various geographic sites and health systems, aimed at determining how the characteristics and beliefs of cancer patients and providers and the characteristics of health care systems influence treatment and outcomes. One of the seven teams is a VA consortium of 15 geographically diverse centers. The methods of CanCORS are detailed elsewhere [5]. Briefly, VA patients were eligible if they had a new diagnosis of invasive colon or rectal cancer that was confirmed by pathology. Subjects were enrolled at VA sites from September 2003 through June 2005. A total of 468 patients with CRC were enrolled in the VA consortium.

Data Sources

CanCORS Database—CanCORS collected data via survey and medical record abstraction. The abstraction protocol was established by the consortium and designed for the variety of health care settings where CanCORS was conducted. Experienced medical record abstractors were trained with test cases at centralized training sessions. Inter-rater reliability scores showed strong agreement. The CanCORS abstraction time window was from 3 months prior to until 15 months after the date of a tissue diagnosis of invasive cancer.

Supplemental Medical Record Abstraction—For this study, we supplemented the CanCORS data by systematically abstracting the medical record of all VA CanCORS participants up to 24 months prior to tissue diagnosis. The supplemental abstraction was performed centrally at the Durham VA medical center by the same research personnel that had performed the CanCORS data abstraction for the VA sites. Abstractors used VistAWeb, a program that allows review of the electronic medical record for all VA facilities at which a particular patient has received care. A 5% sample was randomly chosen for repeat abstraction and review. The only relevant result of the second abstraction was that the abstractors had on occasion collected more data than instructed. This over collection did not affect the results as only the per protocol data were analyzed.

Variables

A diagnostic category was assigned during the supplemental medical record abstraction as one of three, a priori determined, mutually exclusive categories based on the initial event. 1) Screen-detected (positive test) FOBT, barium enema, flexible sigmoidoscopy, or colonoscopy 2) Bleeding-detected: any symptoms related to GI bleeding 3) Other: evaluation originally not for abnormal screening test or gastrointestinal (GI) bleeding. This category included subjects with abnormal tests (e.g. laboratory tests, imaging studies) found during the evaluation of any medical concern other than GI bleeding. Patients with non-bleeding GI symptoms (e.g. abdominal pain) and non-GI symptoms (e.g. weakness) were included in the Other category as well as patients with no symptoms but an abnormal test result (e.g. low hematocrit). Non-bleeding GI symptoms have either weak associations or no association with cancer or significant neoplasia on colonoscopy [6,7,8]. Patients with emergent obstruction and/or perforation were excluded because those patients were not expected to have any system delay to analyze. These patients are generally taken for surgical intervention shortly after presentation to the medical system.

The CanCORS database provided the diagnosis date which was defined as the date of a confirmed tissue diagnosis of invasive cancer and also provided patient-level covariates: age, gender, race (which we collapsed into Caucasian and non-Caucasian), marital status (married or not married), income (>$20,000 or ≤ $20,000), education (greater than high school or high school or less), and comorbidity level (none, mild, moderate, or severe using the Adult Comorbidity Evaluation (ACE-27) index [9]. In addition, two facility-level covariates were considered: complexity level and geographical region. Complexity level is an existing VA score that summarizes variables representing volume of veterans served by the facility, availability of specialized services, levels of teaching and research, and patient severity. Facilities are classified into high, medium and low complexity [10]. Study sites were categorized into the regions: West-Mid West (Chicago-Hines, Chicago-Lakeside, Indianapolis, Minneapolis, Seattle, Tucson), South (Atlanta, Biloxi, Houston, Nashville, Temple), and Atlantic Coast (Baltimore, Brooklyn, Durham, Manhattan).

Outcomes

Time to diagnosis was defined as the time from initial event until the diagnosis date. Initial event date was defined as the abnormal screening test result date (screen-detected) or the first medical visit documenting symptoms of gastrointestinal blood loss (bleeding-detected) or the abnormal test result date for evaluations that were originally to investigate symptoms other than GI blood loss or abnormal test results found incidentally on routine testing of asymptomatic patients (other).

Stage at diagnosis was obtained from the CanCORS database where it was classified as stage I, II, III or metastatic. For this analysis, these classifications were collapsed into early stage (stage I or II), and late stage (stage III or metastatic).

Statistical Analysis

The primary outcome, time from first relevant medical visit or abnormal test date to tissue diagnosis, was analyzed using Cox proportional hazards regression modeling. Potential predictors included patient demographics, diagnostic classification, and facility characteristics. The secondary outcome, stage at diagnosis, was analyzed using logistic regression modeling. For each outcome, the initial focus was on unadjusted models examining the association between each characteristic and the outcome separately. Characteristics associated with the outcome (p-value < 0.25) were included in multivariable models. The exceptions were race and time to diagnosis. Race was included in both multivariable models because of prior evidence of poorer outcomes in CRC for minority patients. Time to diagnosis was included in the stage at diagnosis model because of the importance of assessing whether or not diagnostic delay impacted clinical outcomes.

As per the CanCORS consortium protocol, multiple imputation was used to address item non-response for survey-based variables (income and education). The imputation was performed centrally by the CanCORS Statistical Coordinating Center [11]. Missing survey data values in the imputed data sets reflect individuals who did not participate in the survey (due to either survey refusal or death prior to survey). For unadjusted modeling, the first (of a total of 5) imputed datasets was used.

For the Cox proportional hazards multivariable model, the inverse of the hazard ratios has been reported to facilitate meaningful clinical interpretation of estimates as “delay factors”. A delay factor greater than 1.0 indicates an association with a longer time to diagnosis compared to the reference category; a delay factor less than 1.0 indicates an association with a shorter time to diagnosis compared to the reference category. Odds ratios are presented for the logistic regression multivariable model. For both outcomes of interest, age in years was

modeled as a continuous variable. However, the delay factor or odds ratio (for the proportional hazard or logistic regression model respectively) for age was reported in decade increments to have a more meaningful clinical interpretation.

Model assumptions were assessed for both multivariable models. For the proportional hazards model, the Kolmogorov supremum test was used to check the proportional hazards assumption. For the logistic regression model, the linearity in the logit assumption was checked by examining quartiles of the continuous variables in the model as suggested by Hosmer and Lemeshow [12].

Data analysis was conducted at the Durham VA Medical Center, the coordinating site for VA CanCORS. CanCORS survey dataset version 1.9 and medical records dataset version 1.8 were used for all analyses. Statistical analyses were performed using SAS for Windows Version 9.1 (SAS Institute, Cary, NC). The CanCORS Steering committing approved this study as did the Durham VA Institutional Review Board and Research and Development Committee.

Results

Sample Characteristics

Of the 468 enrolled subjects in VA CanCORS with CRC, 21 (4.5%) presented emergently and were excluded from further analysis. Characteristics of the sample of 447 are listed in Table 1. As is typical for a VA population, the subjects were almost all men, but were otherwise diverse with respect to race, comorbidity, and marital status. Neither income nor education (the survey variables which required imputation) met criteria for inclusion in multivariable modeling for either outcome. Therefore, there was no need to incorporate imputed data in the final models [13]. Two potential predictor variables were found to have little variation and were therefore also excluded from modeling. These were gender because of the small number of female participants (n=10) and complexity score because 14 of the 15 sites were high complexity.

Time to Diagnosis

The median times from initial event to diagnosis were 91 days (range 0–726 days; IQR 34–268 days) for screen –detected cancers, 74 days (range 0–731 days; IQR 22–150) for bleeding –detected cancers, and 73 days (range 0–727 days; IQR 22–210) for other (Table 2). In the multivariable model age, comorbidity, and geographic region were associated with time to diagnosis (Table 2). Older age and any comorbidity level (compared to no comorbidities) were associated with a longer time to diagnosis. The South and West-Midwest regions were associated with a shorter time to diagnosis compared to the Atlantic region.

Stage at Diagnosis

The stage was III or IV for 57% of the sample. The proportion of late stage cancer by subgroups and the multivariable model results for diagnosis with late stage cancer are shown in Table 3. An odds ratio (OR) greater than 1.0 indicates a greater risk of late stage (III/IV) at diagnosis. In the multivariable model only diagnostic category was associated with stage (p-value<0.001). Compared to screen-detected, bleeding-detected and other diagnostic categories were associated with an increased risk of late stage disease at diagnosis. Stage at diagnosis was not associated with either time to diagnosis (p-value= 0.47) or geographic region (p-value =0.09).

Discussion

Our results indicate that there is variation within the VA health system regarding the time from initial clinical event until the diagnosis of CRC. Predictors of a longer period until diagnosis were older age, the presence of comorbidities, and geographic region.

A single VA facility study examining medical system delay from the view point of missed opportunities (symptoms, signs, abnormal tests) that should have prompted an endoscopic evaluation for cancer, found that age > 75 years, coronary artery disease, and congestive heart failure were associated with a higher likelihood of a missed opportunity. The missed opportunities, in turn, were often associated with dramatically longer lag times until endoscopic referral [14]. These results are consistent with this study's findings of increased time to diagnosis for older patients and those with comorbidities. The other medical problems of, particularly, older patients could distract physicians from investigating GI symptoms or abnormal tests. Physicians could be hesitant to refer older patients to colonoscopy because of the higher complication rate in this population or could be biased against treating the elderly more generally. Alternatively, older patients and those with comorbidities could be more likely to become acutely ill and require cancelling and rescheduling of tests or procedures. The retrospective design of both studies is not able to distinguish among these possibilities.

We found regional differences in making a timely CRC diagnosis. The different results among the prior single center VA studies could, in part, reflect regional differences. Whether a shorter time to diagnosis reflects more efficient ordering of tests and consults or more readily available resources to carry out those orders is unknown. By the global resource measure of complexity level, all of the sites were roughly equivalent. It is likely, however, that local resources and the local balance of supply and demand for specific services relevant to CRC diagnosis do differ across regions and individual facilities. Some regional variation in time to diagnosis may be acceptable because stage at diagnosis was not associated with time in the medical system until diagnosis. This does not, however, account for other outcomes such as patient satisfaction.

As noted earlier, research results have been inconsistent regarding the presence and, if present, direction of an association between delay and cancer stage or survival [2]. Differences in results may be related to differences in study design and setting. Even within the VA healthcare system one single center study found that a longer time from colonoscopy referral (for abnormal tests, symptoms or family history) to endoscopic diagnosis of CRC was associated with a less advanced cancer stage and decreased mortality [3] while another single center study found that a longer time from positive FOBT until colonoscopy was associated with increased risk of finding neoplasia on endoscopy [15]. The average time to endoscopy was 41 days in the first and 236 days in the second Design differences between the studies that likely contributed to the different results included that one began with patients who had a diagnosis of colorectal cancer and searched backwards in the medical record examining referral to colonoscopy for a variety of indications [3] while the other began with consecutive patients with a positive FOBT and followed them forward in the medical record [15)]. Both of those centers participated in VA CanCORS. The range of delay observed in our study is unlikely to result in a shift in stage given the natural history of CRC; however, that may not be the only outcome of interest to patients and providers.

Our results have implications for VA and non-VA populations. Our findings support the equity of the VA system with respect to race and colorectal cancer detection. Regional differences in health care spending and resource allocations have been previously documented using Medicare data [16,17,18]. We anticipated that geographic differences

would be attenuated in the VA system because of its centralized structure, but local resources likely play a large role. The potential barriers to a timely diagnosis for older patients are not necessarily a reflection of the VA system, but likely an issue in non-VA populations as well. Finally, the finding that screen-detected cancers are more likely to be early stage confirms the real world effectiveness found in the trials and studies of screening efficacy.

Our study has several strengths. The study includes a large sample of patients from 15 VA medical centers whereas prior VA studies were conducted in a single center. The chart abstraction used standardized protocols to collect data from a comprehensive, linked electronic medical record that included primary and subspecialty care at any VA facility and provided clinical details not available in administrative data sets. The cancer diagnoses were confirmed with histology unlike some studies which used tumor size as a proxy for malignancy.

There are also limitations of this study in design and available data. Additional patient factors, such as distance from VA facility, could be important, but were not available. Patient delay was not assessed because it was not consistently recorded in the medical record. More importantly, patient delay is not directly relevant for diagnoses initiated by a positive screening test or by the evaluation of another medical concern. The quality of the data abstraction is not completely known; however, the use of experienced abstractors, centralized training, and standardized protocols give us confidence in the validity of the data. In addition, the quality assessment of the supplemental data abstraction also support the quality of the VA CanCORS data which were abstracted the same research personnel. Finally, we did not have data to investigate other potential adverse outcomes of delayed diagnosis, such as decreased patient satisfaction or increased anxiety.

Patients with symptoms other than GI bleeding had as their initial event the first abnormal test (e.g. CT scan for back pain). While this approach is straightforward for non GI symptoms, it could be argued that a patient with any GI symptom should have had the first documentation of that complaint as the initial event. The justification for our approach is the dearth of convincing evidence that non-bleeding GI symptoms are strongly predictive of cancer or significant neoplasia (e.g. large adenomas). In a study of consecutive colonoscopies 13% of patients with bleeding had cancer or large adenomas (>1 cm) compared to 2% of patients with other GI symptoms which is the expected prevalence in a screening population [6]. A VA study reported that colonoscopic findings for constipation were similar to findings in an asymptomatic screening population [8]. Finally, a multicenter study observed the same prevalence of polyps and masses >1 cm during colonoscopies for non-bleeding GI symptoms as for asymptomatic patients undergoing screening [7]. Rather than mandate specific evaluations to investigate cancer for every GI symptom, efforts should focus on evaluation of bleeding symptoms and, most importantly, performing age-appropriate CRC screening.

Our results do not support current policies for wait time benchmarks such as 60 days from a positive FOBT until colonoscopy or 30 days to see a new consultation. We recognize, however, that policy benchmarks may reflect other considerations such as perceptions of customer service and satisfaction. Future research should directly investigate the impact of wait times on outcomes such as patient satisfaction, anxiety, and adherence to physician recommendations. If a 3 or 4 month wait time does not negatively impact these outcomes compared to a 1 or 2 month wait time then, it may be a better use of resources to improve the screening rates among asymptomatic patients. In this study having a cancer diagnosed via screening was the only factor associated with stage at diagnosis, but only 39% of participants were diagnosed via screening. Although screen-detected patients could have had

slower growing disease, screening practice guidelines are based, in part, on prospective randomized trials which also found screening to detect cancer at an earlier stage [19,20,21]. Future research should also address why over half of VA patients were not diagnosed via screening and investigate the process of colorectal cancer diagnosis in other medical systems as well. Our results support that it makes an important clinical difference whether a person is diagnosed when asymptomatic or after symptoms or abnormal tests are noted.

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Table 1

Sample characteristics of CRC patients diagnosed during 2003–2005 in 15 VA facilities

Characteristic	Total* (n=447)
Age in years (mean ± SD)	67 ± 10.90
Male (%)	437 (98)
Caucasian (%)	295 (66)
Married (%)	238 (53)
Income (≥ $20K; %)	182 (41)
Education (> high school; %)	134 (30)
Diagnostic Category (%)	
Screen-detected	175 (39)
Bleeding-detected	123 (28)_
Other	149 (33)
Comorbidity (ACE-27) (%)	
None	66 (15)
Mild	170 (38)
Moderate	106 (24)
Severe	105 (23)
Geographic Region (%)	
West-Midwest	155 (35)
South	165 (37)
Atlantic	127 (29)

* This represents the analytic cohort (Total of n=468 were enrolled: n=21 emergent cases excluded.

Missing data survey refusal or nonresponse or, death prior to survey: education (n=111; 25%), income (n=116; 26%).

Abbreviations: VA, Veterans Affairs; CRC, colorectal cancer; SD, standard deviation; ACE-27, Adult Comorbidity Evalutation-27 Scale.[10]

Table 2

Patient and facility characteristics associated with time to diagnosis for VA colorectal cancer patients: unadjusted median time to diagnosis and adjusted delay factor from multivariable Cox PH analysis

Characteristic	Median Days to Diagnosis	Delay Factor^	95% CI	P-value*
Age in decades		1.15	1.05–1.27	0.003
Caucasian Race	75	0.91	0.75–1.12	0.39
(reference = Non-Caucasian)	85			
Diagnostic Category (reference=Screen-Detected)	91			0.84 ^{r}
Bleeding-Detected	74	0.97	0.76–1.24	0. 83
Other	73	0.93	0.74-1.17	0.55
Comorbidity (ACE-27; reference=none)	41			0.005 ^{r}
Mild	98	1.69	1.27–2.26	<0.001
Moderate	77	1.38	1.00–1.91	0.05
Severe	86	1.38	1.00– 1.90	0.05
Geographic Region (reference=Atlantic)	115			<0.001 ^{r}
West-Midwest	58	0.61	0.47–0.78	<0.001
South	81	0.67	0.53–0.86	<0.001

*P-value based on multivariable Cox proportional hazards regression model; gender, education, race, income and marital status were not included in the multivariable model. Final N for model was n=447.

^Delay Factor is mathematically equal to the inverse of the hazard ratio and is intended to provide a more meaningful clinical interpretation of the impact of characteristics on the outcome; a delay factor greater than 1 indicates a longer time to diagnosis.

^{r}P-value for the aggregate effect (type 3 Wald statistic) of characteristic on outcome.

The proportional hazards assumption was checked and not violated.

Abbreviations: VA, Veteran's Affairs; CI, confidence interval; ACE, Adult Comorbidity Evalutation-27 Scale [10].

Table 3

Patient and facility characteristics associated with late stage (stage III or IV) at diagnosis in 445 VA patients with colorectal cancer: unadjusted percentage of late stage and adjusted odds ration from multivariable logistic regression analysis

Characteristic	% Late Stage	Odds Ratio	95% CI	P-value*
Age in decades		0.97	0.80–1.16	0.72
Caucasian Race	44		0.60–1.38	0.64
(reference = Non-Caucasian)	51			
Diagnostic Category (reference=Screen-Detected)	35			<0.001 ^{r}
Bleeding-Detected	55	2.38	1.44–3.92	<0.001
Other	52	2.12	1.34-3.37	0.001
Comorbidity (ACE-27) (reference=none)	58			0.47 ^{r}
Mild	44	0.69	0.38–1.28	0.24
Moderate	46	0.65	0.34–1.25	0.19
Severe	43	0.60	0.31–1.15	0.12
Geographic Region (reference=Atlantic)	50			0.09 ^{r}
West-Midwest	41	0.58	0.35–0.97	0.04
South	49	0.87	0.53–1.42	0.58
Time to Diagnosis (reference=0–30 days)	50			0.47 ^{r}
31–90 days	47	0.90	0.53	0.70
91–180 days	40	0.63	0.34	0.14
>180	46	0.93	0.54	0.80

*P-value based on multivariable logistic regression model; gender, education, race, income and marital status were not included in multivariable model. Final N for model was n=445 (two participants were missing stage).

^{r}P-value for the aggregate effect (type 3 Wald statistic) of characteristic on outcome.

The linearity in the logit assumption was checked and not violated.

Abbreviations: VA, Veteran's Affairs; CI, confidence interval; ACE, Adult Comorbidity Evalutation-27 Scale.