RESEARCH

Colorectal Adenoma Detection Rate in Northeast Texas – Outcome from Community Service Project Using the Fecal Immunochemical Test and Colonoscopy

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ABSTRACT

Colorectal cancer (CRC) is the fourth most frequently diagnosed cancer in the United States. CRC incidence rates in Northeast Texas, a primarily rural region of the state, far exceed state and national averages. The current study sought to determine the proportion of polyps found in a sample of 5,391 individuals living in Northeast Texas using either colonoscopy or fecal immunochemical testing. In addition, the role of insurance to CRC screening was also investigated. An adenomatous polyp was detected in 44.7% participants in the colonoscopy group and in 2.6% of participants undergoing FIT testing. Additionally, participants in the colonoscopy group who were un- or under-insured were 30% more likely to have an adenomatous polyp detected. While a larger proportion of participants had an adenomatous polyp detected in the colonoscopy group, many including the un- or under-insured are not able to afford, at which point FIT testing may be a better option.

KEYWORDS:

Colorectal cancer; adenoma; rural; colonoscopy; fecal immunochemical test

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INTRODUCTION

Northeast Texas is a primarily rural, medically underserved, region of Texas with many health disparities (Nehme et al., 2016). A recent report published on the health status of this region found that if Northeast Texas was its own state, it would be ranked 45th in all-cause mortality (Nehme et al., 2016). Access to primary or specialty care in this underserved region is limited due to a lack of providers. In addition other barriers to care exist, such as distance to specialty care, high rates of poverty, and an older population (Nehme et al., 2016). Around 21% of Northeast Texas adults report not visiting a doctor in the past 12 months due to cost. One such condition that disproportionately affects this area, primarily affects older adults and requires regular screening for prevention is colorectal cancer (CRC).

CRC is the fourth most frequently diagnosed cancer in the United States (U.S. Cancer Statistic Working Group, 2016) with an age-adjusted incidence rate of 38.27 per 100,000 (National Cancer Institute, 2017a). While these rates are similar to those observed in the state of Texas (38.1; Texas Cancer Registry, 2018b), rates of CRC in the primarily rural region of Northeast Texas (Regions 4 and 5) far exceed the state rate and national averages (age adjusted incidence in Region 4 = 43.3, Region 5 = 43.6; Texas Cancer Registry, 2018b) This follows a similar trend of CRC mortality, where rates in Northeast Texas (15.8 – 16.9; Texas Cancer Registry, 2018a) far exceed the state (14.4; Texas Cancer Registry, 2018a) and national (14.1; National Cancer Institute, 2017b) averages. As in most cancers, CRC morbidity and mortality can be reduced or even prevented if CRC is diagnosed early.

CRC typically develops from adenomatous polyps (American Cancer Society, 2017). These polyps are precancerous polyps that can develop into CRC. Therefore, the detection and subsequent removal of adenomatous polyps prevents CRC (American Cancer Society, 2018). This has been achieved through preventive screenings with the use of the fecal immunochemical test (FIT) and colonoscopy. However, with a high poverty rate, difficulty accessing specialty care (distance to provider and lack of provider), and an older population in Northeast Texas, receiving preventive care for CRC can be challenging.

Colonoscopy is invariably considered the gold standard for CRC screening (Friedrich et al., 2015; Lieberman et al., 2012). Colonoscopy is able to identify and remove polyps that can be divided into the following types: 1) hyperplastic (polyps with no malignant potential), 2) adenomatous (polyps with malignant potential), and 3) malignancies (Lieberman et al., 2012). Detection and removal of adenomatous polyps can prevent these polyps from progressing into malignancies and hence reduce or prevent mortality (Lieberman et al., 2012). However, colonoscopy is an invasive procedure, with many barriers that tend to prevent many individuals from completing the procedure. For example, the need for sedation, arranging transportation to and from the hospital, missing work, etc. which are typical experiences with the procedure.

FIT testing, on the other hand, has attracted a lot of interest and seemed to be better accepted (Segnan et al., 2007) by the general public. This procedure is less invasive and less time consuming than colonoscopy but is not complete CRC screening method on its own (Quintero et al., 2012). With FIT, participants send a stool sample to

a laboratory from the convenience of their home. The test identifies the stool sample as either normal or abnormal. If the test comes back abnormal, participants are urged to undergo a colonoscopy in order to detect and remove potential polyps. Thus, this test enables only participants with abnormal FIT test results to have undergoing the less desired colonoscopy.

The current goal set by the U.S. Department of Health and Human Services in the Healthy People 2020 is to achieve a 70.5% CRC screening rate. However, even with the availability of both screening methods, CRC screening rates remain suboptimal in the general public (62.4%; U.S. Department of health and Human Services, 2018) and in rural communities (58.2%; U.S. Department of Health and Human Services), with rates being even lower in Northeast Texas (44.63%; Hall, 2018). They are even much lower among the uninsured (25.1%). The high CRC prevalence and yet low screening rates in the Northeast Texas region is a growing concern. While the reason for this remains elusive, a few factors typical of a rural setting, may potentially be incriminated. Having other health burdens coupled with low health literacy, preventive care is hardly a priority. The region is vast in size and consists of rural counties with few small metropolitan statistical areas. Poor access to safe and affordable transportation presents an extra challenge to residents who must often travel long distances to a healthcare facility. Due to fewer available providers compared to urban settings, waiting periods to get an appointment is generally longer (Texas Medical Board, 2017). The region is predominantly inhabited by low-to moderate income individuals and families living below the federal poverty line, (The Henry J. Kaiser Family Foundation, 2014) making it difficult for them to afford health insurance.

CRC detection rates for rural residents are not well established. In addition, with the emergence of FIT testing, detection rates for rural residents have not been established. Particularly, the role of insurance to CRC screening in this setting has never been investigated. As a consequence, the current study sought to:

1. Investigate CRC adenoma detection rates in primarily rural Northeast Texas by FIT test and colonoscopy.
2. Examine the impact of not having health insurance on adenoma detection rates.

MATERIALS AND METHODS

The study was part of a community outreach program for CRC screening in 19 counties of Northeast Texas organized by the Northeast Texas Center for Rural and Community Health (NETCRCH) at the University of Texas Health Science Center at Tyler (UTHSCT). The project was funded by the Cancer Prevention Research Institute of Texas (CPRIT) and was deemed exempt by the UTHSCT Institutional Review Board (IRB). Study participants were recruited either by referrals from UTHSCT clinics (general population) or through community outreach events organized by NETCRCH which targeted un- or under-insured individuals. With the exception of some small metropolitan statistical areas, the catchment area consisted of rural communities with little or no access to public transportation. Data was collected between 2014 and 2017. It includes all colonoscopies and FIT tests performed at UTHSCT.

A resident of Northeast Texas was considered eligible to participate in the study if the resident

was 44 to 76 years of age, spoke English or Spanish, and was currently undergoing a colonoscopy and/or FIT test. Individuals previously diagnosed with CRC were considered ineligible.

Figure 1 describes the flow of participants through the study. The final study sample consisted of 5,391 participants. If participants were seen at the UTHSCT clinics and met all inclusion/exclusion criteria, they were recommended/referred for colonoscopy and/or FIT test regardless of payer source. Participants were offered colonoscopy and/or FIT test based on their preference and/or provider recommendation. If participants were deemed un- or under- insured and unable to pay for services, screenings were provided free-of-charge, as a part of the CPRIT grant, otherwise they had to pay for their screening. Participants recruited through clinics or outreach events that were a part of the CPRIT grant were provided an additional gift card of $20 for transportation upon completion of a colonoscopy. Participants who elected to take the FIT test were scheduled for colonoscopy if they had an abnormal FIT result (and subsequently received the same $20 gift card for transportation upon completion of colonoscopy).

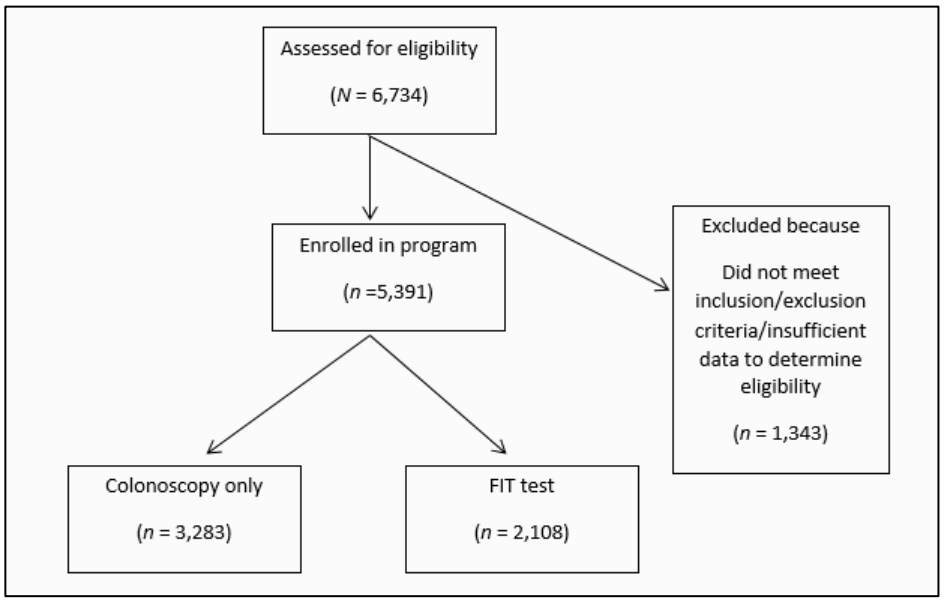

Figure 1. CONSORT Diagram

Outcome and other variables of interest

The key outcome variables of interest for this study were the results of the FIT test and colonoscopy.

FIT test

Participants who completed a FIT test received a normal or abnormal result. If an abnormal result was received, participants were scheduled for a follow-up colonoscopy. For analytical purpose, the results of the FIT test were categorized as: 1) normal, 2) hyperplastic polyp only, 3) adenomatous polyp, 4) malignancy and 5) abnormal FIT test result, but no follow-up result with colonoscopy.

Colonoscopy

Colonoscopy outcomes were divided into four categories: 1) normal, 2) hyperplastic polyp only, 3) adenomatous polyp, and 4) malignancy.

Demographic and medical information

Demographic (gender, race/ethnicity) and medical information (insurance status, family history of cancer) were gathered through patient record and electronic medical record. Insurance status, gender, previous screening, and family history of colon cancer were coded as dichotomous, race/ethnicity was coded as Non-Hispanic White, Non-Hispanic Black, Hispanic, and Asian. Meanwhile age was retained as continuous.

Statistical Analysis

Data was analyzed using Statistical Package for Social Science (SPSS) version 23.(IBM corporation, 2015) Descriptive statistics are reported for demographic and medical variables, including prevalence rates of neoplasms (Table 1).

Table 1. Demographic and Other Distributions of Study Participant Who Originally Opted for FIT and Colonoscopy for Colorectal Cancer Screening (Outcome of a Northeast Texas Community Service Project).

Variable	Overall *n* (%)	FIT test** *n* (%)	Colonoscopy *n* (%)	p-value*
Overall	5,391	2,108 (39.1)	3,283 (60.9)	<0.001
Age Mean (SD)	59.0 (6.6)	57.5 (5.6)	60.0 (6.9)	<0.001
Gender				
Male	1,978 (36.7)	665 (31.5)	1,313 (40.0)	<0.001
Female	3,413 (63.3)	1,443 (68.5)	1,970 (60.0)	
Race/Ethnicity				<0.001
Non-Hispanic White	3,057 (56.7)	1,081 (51.3)	1,976 (60.2)	
Non-Hispanic Black	1,119 (20.8)	332 (15.7)	787 (24.0)	
Asian	40 (0.7)	16 (0.8)	24 (0.7)	
Hispanic	1,170 (21.7)	676 (32.1)	494 (15.0)	
Missing	5 (0.1)	3 (0.1)	2 (0.1)	
Insurance Status				<0.001
Un- or Under- Insured	3,033 (56.3)	1,962 (93.1)	1,071 (32.6)	
Insured	2,358 (43.7)	146 (6.9)	2,212 (67.4)	
Previous screening				<0.001
No	2,429 (45.1)	1,218 (57.8)	1,211 (36.9)	
Yes	1,667 (30.9)	439 (20.8)	1,228 (37.4)	
Did not provide an answer/missing	1,295 (24.0)	451 (21.4)	844 (25.8)	
Family history of colon screenings				< .001
No	4,210 (78.1)	1,546 (73.3)	2,664 (81.1)	
Yes	463 (8.6)	97 (4.6)	366 (11.2)	
Did not provide an answer/missing	718 (13.3)	465 (22.1)	253 (7.7)	
Details of test results				
Normal		1,913 (90.7)	1,472 (45.2)	
Hyperplastic polyp		11 (0.5)	285 (8.8)	
Adenomatous polyp		53 (2.6)	1,467 (45.0)	
Malignancy		2 (0.1)	33 (1.0)	

Abnormal FIT test result, but no follow-up with colonoscopy		129 (6.1)		
Missing ǂ			26 (0.9)	

**p-value for Age was based on analysis of variance, and for the rest were based on the Pearson's chi-square test.*
***FIT: Fecal Immunochemical Test. Of the 247 who tested abnormal, 129 failed to follow-up with colonoscopy and 118 underwent colonoscopy follow-up (resulting in 52 normal and 66 abnormal results) with details as specified in the table.*

ǂ Final result for colonoscopy not available due to poor bowel prep

Demographic and other differences in the distribution of the results of the FIT test and colonoscopy were assessed using the Pearson's chi-square test or a binomial test of proportion. The multinomial logistic regression model that controlled for gender, age, race/ethnicity, previous screening, and family history of colon cancer was applied to generate odds ratio (OR) and 95% confidence interval (CI) that assesses the likelihood that individuals who received any of the abnormal screening results (FIT and colonoscopy) were un-/under-insured compared to those who were insured.

RESULTS

Descriptive Statistics

The general characteristics of the study sample is depicted in Table 1. Of the 5,391 participants, 3,057 (56.7%) were non-Hispanic White, 1,119 (20.8%), non-Hispanic Black, 1,170 (21.7%) Hispanic, 40 (0.7%) Asian, and 5 (0.1%) were of unknown race/ethnicity. The mean age was 59 ± 6.6 years. They were predominantly females (n = 3,413, 63.3%), with a slight majority being un- or under-insured (n = 3,033, 56.3%). A family history of colon cancer was identified in 463 (8.6%) individuals.

Originally, a majority of the study participants elected to undergo a colonoscopy screening (3,283, 60.9%) compared to FIT test (2,108, 39.1%), a statistically significant difference (p < 0.001). There was also statistically significant differences in the demographics of these individuals. The FIT group was generally younger (p < .001), with fewer males (p <0.001) and being un- or under- insured (p < 0.001), compared to the colonoscopy group. Finally, a larger proportion of colonoscopy results (1,785, 54.2%) were found to be abnormal than FIT test results (195, 9.3%) as compared to having a normal result, a statistically significant difference (p <0.001).

FIT Test Results

Of the 2,108 who underwent FIT testing originally, 247 (11.7%) had abnormal results. Of those deemed abnormal, subsequent colonoscopies identified both normal and abnormal outcomes. Of the 247 with abnormal FIT results, 129 (52.2%) receiving an abnormal result, but failed to undergo a colonoscopy for further diagnosis. The remaining 118 (47.8%) who opted for a follow-up colonoscopy screening reported the following results: 53 (44.9%) normal, 11 (9.3%) hyperplastic polyp, 54 (45.8%) adenomatous polyp, and 2 (1.6%) malignancies (Table 1). Finally, likelihood ratio tests revealed a non-significant effect of insurance status on FIT test result (p = 0.419).

Colonoscopy Results

Results of colonoscopy revealed, 1,472 (44.8%) had a normal results, 285 (8.6%) had a hyperplastic polyp, 1,467 (44.7%) had an adenomatous polyp, and 33 (1%) had a malignancy (Table 1). Likelihood ratio tests revealed a significant difference in colonoscopy outcome among the insured and un-/under-insured, p = 0.047. There was a statistically

significant 30% increased odds of having an adenomatous polyp among the un-/under-insured as compared to the insured [OR = 1.30, 95% CI: 1.05, 1.61]. No significant differences were found for those with a hyperplastic polyp or a malignancy. Results are displayed in Table 2.

Table 2. Odds Ratios and 95% Confidence Intervals of Multinomial Logistic Regression Results Examining Effect of Insurance Status on Colonoscopy Group.

	Colonoscopy group results		
Variable	Hyperplasia	Adenoma	Malignancy
Gender	0.95 [0.70, 1.29]	0.72 [0.60, 0.86]*	1.28 [.48, 3.37]
Age	0.99 [0.96, 1.01]	1.04 [1.02, 1.05]*	1.04 [.97, 1.13]
Family History of Colon Cancer	1.14 [0.75, 1.73]	1.03 [0.79, 1.34]	1.03 [.29, 3.61]
Previous screening	1.43 [1.03, 2.05]*	0.91 [0.73, 1.13]	0.93 [.31, 2.78]
Non-Hispanic Black	0.78 [0.54, 1.11]	0.85 [0.69, 1.05]	0.47 [.13, 1.63]
Asian	0.38 [0.05, 2.97]	0.45 [0.17, 1.23]	
Hispanic	0.53 [0.33, 0.85]*	0.61 [0.47, 0.80]*	0.26 [.05, 1.23]
Insurance status	0.98 [0.69, 1.39]	1.30 [1.05, 1.61]*	0.60 [.20, 1.76]

Note. Race/ethnicity was compared to Non-Hispanic White; Results of colonoscopy group are compared to normal results; Insurance status coded as 0 for insured and 1 for uninsured; family history of cancer coded as 0 for no and 1 for yes; previous screening coded as 0 for no and 1 for yes; results with no odds ratio and 95% confidence interval entered were not able to be calculated due to low sample sizes; * p <0 .05

DISCUSSION

Tests that can identify adenomatous (precancerous) polyps before they become cancerous are crucial to reduce health disparities among rural residents. The current study found a very high adenoma detection rate. While results differ from study to study, different studies report prevalence rates as low as 1.3% (Gupta et al., 2013), or as high as 58%, (Øines et al., 2017) although most rates vary between 25 to 50% (Bretthauer et al., 2016; Giacosa et al., 2004; Hilsden et al., 2016; IJspeert et al., 2015; Øines et al., 2017; Quintero et al., 2012),depending on country where study was conducted or other factors. However, studies focus on adenoma detection rates identified via colonoscopy in primarily urban settings and research among underserved rural populations is sparse. Further, studies are limited on FIT test adenoma detection rates due to its nascence, especially among underserved rural populations. The high prevalence rates detected add to the current literature on rural populations and are important to note, especially when compared to a recent randomized control trial conducted in a different part of the state. Specifically, a similar study conducted in southern Texas found adenoma detection rates that ranged between .8% for FIT test and 1.3% for colonoscopy (Gupta et al., 2013). While the study did not examine differences among insurance rates and was conducted in a primarily urban setting, the adenoma detection rates for the current study were much higher, with rates ranging from 2.6% for FIT test and 44.7% for colonoscopy. These results shine to light: 1) the large disparity in adenoma detection rates when using a FIT test as compared to a colonoscopy and 2) the large adenoma detection rate in this primarily rural setting.

While the adenoma detection rate was lower for FIT testing when compared to colonoscopy, a previous study found that the FIT test results are

not as high as colonoscopy (Quintero et al., 2012). However, the discrepancy between adenoma detection rate between FIT and colonoscopy varied only by a small amount (.9% for FIT vs. 1.9% for colonoscopy), (Quintero et al., 2012) while the current study found a much larger variation. Other potential explanations may be that for example the FIT test group consisted of participants who were younger and more likely to be female, both factors that contribute to adenoma detection (Corley et al., 2013).

Nevertheless, the FIT test provides many practical benefits that warrant its use, especially among low income populations. First, the FIT test is less burdensome on participants and allows for not having to take off of work or figuring out transportation. Second, it is a far less costly procedure (Corley et al., 2013) that can therefore be disseminated to a larger public health population. However, it is suggested that a FIT test need be completed every year (Corley et al., 2013). This might prove to be burdensome for many, as compared to a colonoscopy which needs to be completed every few years (depending upon physician recommendation for follow-up). Due to this burden the un-/under-insured may not complete FIT testing as often as recommended after their initial FIT test, with the potential of future adenomas or malignancies being undetected until it is too late.

Proportions of adenomas detected were higher for colonoscopies, with almost half of all participants having an adenomatous polyp detected. The removal of these polyps will help to hopefully reduce the rate of colorectal cancer among this population, although such outcomes could not be surmised by the current study.

Being un-/under-insured played a very important role in colonoscopy, but not FIT test results. The un-/under-insured were more likely to have an adenomatous polyp detected for colonoscopy. While insurance status did not have an effect on FIT test results, a large proportion of participants with abnormal results failed to follow-up for subsequent colonoscopy. An abnormal FIT test result without follow-up colonoscopy to further diagnose and/or remove potential polyps deems the FIT test impractical. It is especially important to note since all FIT tests and colonoscopies were provided free-of-charge to the un-/under-insured and a transportation gift card was provided for the un-/under-insured who underwent a colonoscopy, therefore reducing the additional barrier of cost to this population. However, we were not able to reduce the barrier of having to take time off of work to undergo a colonoscopy.

IMPLICATIONS AND LIMITATIONS

The current research has implications for public health policy and/or initiatives in rural, underserved regions. Both FIT test and colonoscopy proved to have many benefits, as well as disadvantages. While colonoscopies allow participants to undergo just one procedure and allow for removal of polyp at the time of the visit, they are costly and may not be able to be implemented on a larger scale for the un-/under-insured. On the other hand, FIT tests are not cost prohibitive and are able to reach a larger population, especially among the un-/under-insured. It is important that if public health programs elect to disseminate a FIT test program that emphasis be placed on the importance of retesting the same individuals every year, to insure a higher efficacy of the test. This warrants a cost-effectiveness or return-on-investment analysis to

assess the efficacy of a FIT test outreach program as compared to a colonoscopy outreach program in order to see true implications for public health policy and/or initiatives.

The current study was not able to examine differences among those with an abnormal FIT test result due to low number of participants receiving a positive FIT test result. However, future research will analyze these differences as well as assess the duration of time to follow-up. The current study was also not able to assess whether the removal of adenomatous polyps resulted in decreased CRC detection. However, this is outside of the scope of the study as follow-up with this patient population will warrant years of future research. Finally, unlike the Gupta et al.(Gupta et al., 2013) study, the current study gave participants the option to choose between colonoscopy and FIT test, which could have resulted in biased results when comparing abnormal rates for FIT as compared to colonoscopy. However, adenoma detection rates were still high for both FIT and colonoscopy when compared to previously mentioned studies and warrant attention (Gupta et al., 2013; Quintero et al., 2012).

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Conflict of interest

The authors declare that no competing or conflict of interests exists. The funders had no role in study design, writing of the manuscript, or decision to publish.

Authors' contributions

Carlton Allen and Paul McGaha contributed to the acquisition of data and the conduct of the project. Karan Singh, Harrison Ndetan, and Gabriela Orsak contributed to the statistical analysis of the project and generated the initial draft of the article.

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