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Longitudinal Adherence to Multi-Target Stool DNA Testing for Colorectal Cancer Screening is Poor

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Introduction

Multi-target stool DNA testing is advised as a second-tier option for colorectal cancer (CRC) screening.1 In the United States, such a test is marketed as Cologuard (Exact Sciences, Madison, WI).2 Current guidelines recommend that Cologuard should be repeated every 3 years after a negative result. Due to a lack of long-term data on compliance with serial testing, we evaluated longitudinal adherence to this mt-sDNA test.

Methods

We performed a retrospective study in a large community healthcare system. All patients (n=615) advised an initial mt-sDNA test in 2016 were reviewed. Patients with a negative test were eligible for the study (n=283); patients with a positive test (n=60) or non-compliance (n=272) were excluded. The primary outcome was longitudinal adherence, defined as the completion of a follow-up mt-sDNA test 2.5-3.5 years after the initial test result. Factors such as gender, age at initial test, race, body mass index (BMI), and insurance type were evaluated to determine their association with longitudinal adherence using logistic regression analysis. The Institutional Review Board determined the study was exempt from review, as it represented a quality improvement study.

Results

283 patients (mean age 66.0 years, 60.4% female, and 77.0% Caucasian) with a negative initial test were included in this analysis. Only 76/283 (26.9%) patients were advised a repeat mt-sDNA test between 2.5-3.5 years after the initial test, and of these, 61 (80.3%) completed the test. Therefore, 61/283 (21.6%) met the primary outcome of longitudinal adherence.

	Compliant with longitudinal mt-sDNA screening, n=61 (%)	Not compliant with longitudinal mt-sDNA screening, n=222 (%)	Odds Ratio (CI)	p-Value
Age, years ± SD	64.8 ± 6.7	66.4 ± 8.9	0.98 (. 95-1.01)	0.20
Male Gender, n (%)	35 (57.4)	136 (61.3)	1.18 (. 66-2.08)	0.58
Race			1.16 (. 73-1.77)	0.51
Caucasian	43 (70.5)	175 (78.8)		
African-American	14 (23.0)	27 (12.2)		
Other/ Unknown	4 (6.6)	20 (9.0)		
BMI, kg/m2 ± SD (n=279)	30.1 ± 7.4	28.4 ± 6.7	1.03 (0.99-1.08)	0.10
Ordering Provider			1.45 (. 69-2.89)	0.31
Physician	48 (78.7)	187 (84.2)		
Non-Physician	13 (21.3)	35 (15.8)		
Insurance Type			1.01 (. 60-1.66)	0.98
Commercial	18 (29.5)	77 (34.7)		
Medicare	43 (70.5)	138 (62.2)		
Medicaid	0 (0)	3 (1.4)		
Other/ Unknown	0 (0)	4 (1.8)		
Mean Interval From 1st Order to 1st Result, days ± SD	41.6 ± 63.7	43.9 ± 53.7	1.00 (. 99-1.00)	0.78

Table 1: Comparison of patients by longitudinal mt-sDNA adherence status at 3 years, with univariate analysis of potentially associated clinical factors.

mt-sDNA, multitarget stool DNA; CI, 95% confidence interval; BMI, body mass index

Table 1 displays the results of univariate analysis for factors potentially associated with longitudinal adherence. None of the

covariates including patient demographics, ordering provider type (physician or non-physician), insurance status, and mean time to completion of the initial mt-sDNA test, were significantly associated with the primary outcome. As such, a multivariate analysis was not performed. Exploratory analyses of age ≥65 years (p=0.91) or BMI ≥30 (p=0.13) also did not demonstrate an association with longitudinal adherence.

9/61 (14.8%) patients who completed a second mt-sDNA test had a positive result; of these only 5/9 (55.6%) pursued a follow-up colonoscopy (1 advanced adenoma, 3 non-advanced adenomas, and 1 without neoplastic findings). Finally, eight patients had their second mt-sDNA test performed outside of the recommended study window of 2.5-3.5 years (1 with early testing [11 months]; 7 with late testing [range 44-50 months]).

Discussion

Evaluation of strategies for colorectal cancer screening must move beyond cross-sectional compliance at a single point in time. Since mt-sDNA testing was only recently approved for CRC screening, longitudinal adherence with this test over multiple time points has not been systemically evaluated. Thus, our analysis represents the first data on the longitudinal adherence to mt-sDNA testing. Our study shows a poor rate of adherence (21.6%) to a second mt-sDNA test, allowing a window of 6 months before and after the guideline-specified testing interval of 3 years. Further, we found no associated factors that might predict a group at higher risk for non-adherence.

Although data on longitudinal mt-sDNA testing are unavailable outside of the present study, previously published data on longitudinal adherence to fecal occult blood testing (FOBT) have similarly shown poor results. A 2016 trial3 comparing longitudinal adherence to either annual FOBT or colonoscopy demonstrated that adherence to FOBT over a 3-year period was just 14%, compared to 38% in the colonoscopy group. Similarly, a study of longitudinal adherence to annual FOBT among United States military veterans demonstrated that only 14.1% subjects completed their FOBT in 4 out of 5 years.4 Additionally, a large retrospective analysis of 151,638 subjects showed that 97,518 (64%) achieved adherence to CRC screening over a 10 year period. Of these, 99.6% achieved adherence by undergoing one or more colonoscopy examinations, whereas only 0.3% were adherent by completing an annual FOBT for 10 years. Extrapolation of our study's 21.6% rate of longitudinal adherence to a 3rd test, which would cover 9 years of screening total, would lead to a theoretical adherence rate of 4.7%.

A related concept that is clinically useful for practitioners is termed 'proportion of time covered' (PTC), proposed by Murphy et al6 in 2018. The concept prioritizes the length of time that a screening modality offers a patient 'coverage' for a negative result; for example, a negative fecal immunochemical test (FIT) would provide 1 year of coverage while a normal colonoscopy would provide 10 years of coverage. Their study analyzed >18,000 patients between the ages of 50 and 60 years eligible for CRC screening, and found that the overall PTC by any screening method was only 29.1%. Among those completing at least one FIT test, 58.8% were not covered for at least some portion of the study period, whereas among those who completed a colonoscopy, only 4.4% of patients were not fully covered during the study period due to an incomplete colonoscopy. Given the post-screening interval of 10 years recommended to a patient with a normal colonoscopy, the findings by Murphy et al are not surprising. Although our study was not designed to perform a similar analysis, we believe the PTC metric would be helpful to assess longitudinal adherence to the mt-sDNA test in future studies.

Our study has several limitations; it was a retrospective study involving a single community-based health system. Due to the relatively short duration of the mt-sDNA test availability (it was approved by the FDA in 2014), data on even longer-term adherence at 6 or 9 years are unavailable. Since colorectal cancer screening is recommended from ages 45-75, assessing compliance with additional mt-sDNA tests would be very important to determine if the drop-off in longitudinal adherence that we observed at 3 years persists over a longer screening period. If this is indeed the case, the mt-sDNA test may not represent a viable strategy to increase compliance with CRC screening as advertised. Instead, efforts towards improved adherence to colonoscopy may be more cost-effective since it would achieve a higher PTC with a single negative examination.

In summary, we demonstrate a poor (21.6%) longitudinal adherence at three years among patients who underwent screening for CRC using the mt-sDNA test.

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