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Alaska Native Patient and Provider Perspectives on the Multitarget Stool DNA Test Compared With Colonoscopy for Colorectal Cancer Screening

Diana G. Redwood[1], Ian D. Blake[1], Ellen M. Provost[1], John B. Kisiel[2], Frank D. Sacco[1], and David A. Ahlquist[2]

Abstract

Objective: Alaska Native (AN) people have among the world's highest rate of colorectal cancer (CRC). We assessed perceptions of AN people and their health care providers of a new take-home multitarget stool DNA test (MT-sDNA; Cologuard) relative to colonoscopy. **Methods:** Cross-sectional surveys of AN people aged 40 to 75 years (mailed) and providers (online). **Results:** Participants included 1616 AN patients (19% response rate) and 87 providers (26% response rate; 57% AN people). Over half (58%) of patients preferred colonoscopy for CRC screening, while 36% preferred MT-sDNA. Unscreened patients were significantly more likely to state a preference for MT-sDNA than previously screened patients (42% vs 31%, $P < .05$) as were younger patients (<60 years old) compared with older patients (40% vs 30%, $P < .05$). Most providers thought that MT-sDNA would improve screening rates (69%), would recommend if available (79%), and be implementable (79%). Perceived barriers differed substantially between patients and providers in both type and magnitude. Leading colonoscopy barriers reported by patients were travel (44%) and bowel preparation (40%), while providers thought that fear of pain (92%) and invasiveness of the test (87%) were the primary barriers. For MT-sDNA, patients' belief that colonoscopy was better (56%) and not knowing how to do the test (40%) were primary barriers, while providers thought stool collection (67%) and having a stool sample in their home (63%) were leading barriers. **Conclusions:** This study found that MT-sDNA has potential acceptability among AN people and their health care providers. Both groups reported a willingness to use MT-sDNA and did not perceive major barriers to its use. This preference was especially true of unscreened and younger patients. The majority of providers indicated they would use MT-sDNA if available and that it would improve CRC screening rates. In this population, where colonoscopy access is limited, MT-sDNA has the potential to improve CRC screening adherence.

Keywords

Alaska Native, Cologuard, multitarget stool DNA testing, colonoscopy, colorectal cancer, screening, adherence, prevention

Introduction

Alaska Native (AN) people experience 2 times higher incidence and mortality from colorectal cancer (CRC) than US whites.[1,2] CRC can be prevented through removal of precancerous polyps or treated more easily if detected early using screening tests.[3-5] Although significantly improved, the AN CRC screening prevalence of 59% is still far from the national Healthy People 2020 goal of 70.5%.[6,7]

Because of high rates of colorectal neoplasia, colonoscopy has become the preferred CRC screening method in the AN population.[8] Colonoscopy, however, is resource intensive, requires specially trained providers, and carries a risk of complications due to adverse reactions to anesthesia or bowel perforations.[9] More than half of the AN population resides in widely distributed and remote roadless regions.[10] In these regions there are 7 Tribal health facilities that

[1]Alaska Native Tribal Health Consortium, Anchorage, AK, USA
[2]Mayo Clinic, Rochester, MN, USA

Corresponding Author:
Diana Redwood, Alaska Native Tribal Health Consortium, 3900 Ambassador Drive, Anchorage, AK 99508, USA.
Email: dredwood@anthc.org

provide colonoscopies, of which only 1 is connected by road to the communities that they serve. Therefore, colonoscopy generally requires travel in small aircraft for the patient and their medical escort, with concomitant costs and time away from work and dependent care. Additionally, colonoscopy appears to have limited effect on incidence or mortality of proximal CRC, which is of concern as over 41% of CRCs in AN people occur in the proximal colon.[11-19] Compared with colonoscopy, take-home stool tests are less expensive, more easily distributed, eliminate the need for bowel preparation, and do not require costly travel or time away from work or caretaking responsibilities. CRC screening using guaiac-based fecal occult blood tests is not recommended for AN people because of false-positive results associated with a high prevalence of *Helicobacter pylori* infection and red meat consumption.[8,20] Another take-home test, the fecal immunochemical test, which identifies intact human hemoglobin in stool, is available in the Alaska Tribal Health System.[8] However, its use has been limited due to tribal leadership concerns that it does not detect precancerous polyps in this increased-risk population.

We previously evaluated the performance of a new take-home stool test, the multi-target stool DNA test (MT-sDNA; Cologuard, Exact Sciences, Madison, WI) in the AN population. Results were very similar to those in a large multicenter screening study; respective detection rates for CRC were 100% and 92% and for large polyps at greatest risk for progression (≥2cm) were 62% and 67% with respective specificities of 93% and 90%.[21,22] MT-sDNA sensitivity for CRC is similar to that reported by colonoscopy, and was significantly higher than the fecal immunochemical test in the AN population.[13-15]

Patient willingness and ability to complete tests as well as provider recommendation are critical factors in improving CRC screening.[23-28] Initial MT-sDNA studies have shown its use increases screening adherence, including among never-screened patients, and its use may actually increase the yield and quality of follow-up colonoscopies.[29-31] In this study we assess the acceptability of MT-sDNA testing compared with colonoscopy among AN people and their healthcare providers. This study serves as a critical step in determining the feasibility and application of MT-sDNA; patient and provider barriers to MT-sDNA and colonoscopy; and provides insights for increasing CRC screening among other rural/remote populations.

Methods

This study was conducted in three rural/remote Alaska Tribal health organization regions from July-September 2017. The Alaska Area Institutional Review Board and relevant tribal research and ethics committees of each participating region approved the study. AN people aged 40 to 75 years (n = 8979) were invited to participate in a mailed survey, which in 2 regions included an invitational cover letter signed by the Tribal health organization's Medical Director. Tribal health organization health care providers (n = 87), including mid-level providers, physicians, and community health aides/practitioners completed the survey online. Patient questions were adapted from the National Cancer Institute's Health Information National Trends Survey[32] and provider questions were adapted from the CRC Screening Practices: Survey of Primary Care Providers.[33-35] Each survey contained 12 items and took about 5 to 10 minutes to complete. Likelihood ratio chi-square tests and Fisher's exact test were used for categorical data using SAS version 9.4 (SAS Corporation, Cary, NC). All analyses were 2-tailed; $P < .05$ was considered statistically significant. Participants with missing data were excluded from the individual variable analysis and no corrections for multiple comparisons were made due to the small number of planned comparisons.

Results

Patient Characteristics

Of the 8580 patients with valid addresses, 1616 patient surveys were completed (19% response rate, range 18%-31%; Figure 1). A total of 21% of respondents were aged 40 to 49 years, 36% were aged 50 to 59 years, 34% were aged 60 to 69 years, and 7% were aged 70 to 75 years. Response rates were similar among men (51%) and women (49%). One-fifth (20%) of screening-eligible patients (men and women aged 40-75 years) had never heard of CRC screening tests and had never been screened. Of those who had heard about screening tests, 98% had heard of colonoscopy. About 22% had heard of take-home stool tests (fecal occult blood test or fecal immunochemical test), while only 16% had heard of MT-sDNA. When patients were asked about CRC screening, most agreed that being screened would make them feel they are doing something positive for their health (87%) or reassured (79%). A small minority reported not needing CRC screening because they feel fine (14%), no family history (9%), or afraid of having cancer (8%). Of note, 18% reported not seeking screening because of not knowing where to go. Men and women did not significantly differ in their general attitudes toward screening except for more men reporting not knowing where to go (21% vs 14%, $P < .05$) and not needing screening because no family history (11% vs 9%, $P < .05$).

Prior CRC Screening History and Reasons for Nonscreening

Over half of patients (58%) reported having been screened for CRC, mostly by colonoscopy (96%). Of the never screened, the top 5 reasons included no reason/never thought

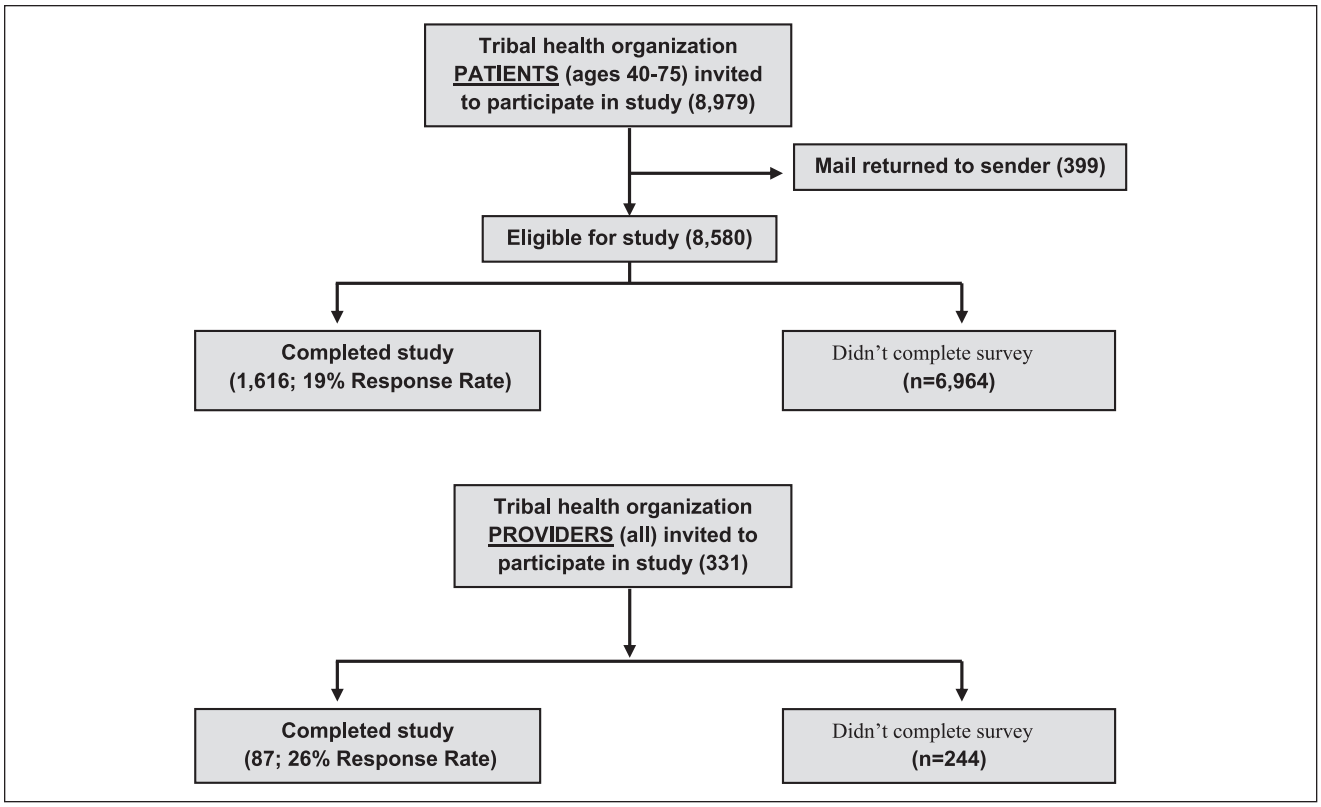

Figure 1. Study flow diagram.

about it (46%); no symptoms (28%); no doctor suggestion (25%); didn't need it/didn't know needed it (21%); and too expensive/no insurance (13%). Less than 10% said they were unscreened because they "hadn't gotten around to it," 8% because they didn't have a doctor, and 7% because of embarrassment or discomfort with the procedure. Participants could choose more than one answer, so results do not total 100%.

Patient Barriers to Colonoscopy and MT-sDNA

All participants (both screened and unscreened) were then asked about specific barriers (ie, conditions that make it difficult to be screened) to either colonoscopy or MT-sDNA, regardless if they were able to overcome those particular barriers to complete their screening. The top barriers reported by those who had ever undergone colonoscopy included colonoscopic preparation laxatives (51%), travel (47%), fear of injury (36%), discomfort with a tube in their rectum (34%), and fear of pain (32%). In contrast, the top barriers reported by those who had never undergone colonoscopy included fear of pain (65%), discomfort with a tube in their rectum (63%), travel (60%), colonoscopic preparation laxatives (57%), and fear of injury (49%). The top colonoscopy barriers overall included travel (44%), colonoscopic preparation laxatives (40%), fear of pain (35%), discomfort with a tube in their rectum (34%), and fear of injury (30%). Overall, 29% said that undergoing anesthesia or having to find a postprocedure escort would be barriers. Less than one-quarter reported taking time off work (23%), the need for dependent care (22%), embarrassment (18%), or the procedure taking too much time (16%) as colonoscopy barriers. Men and women did not differ substantially, although more women than men reported pain (40% vs 31%, $P < .05$) and undergoing anesthesia (33% vs 25%, $P < .05$) as barriers.

A smaller proportion of respondents reported barriers to getting screened using MT-sDNA (13%-53% answered yes to each of the listed barriers) compared with colonoscopy (38%-73%). The top 5 MT-sDNA barriers included belief that colonoscopy is better at preventing cancer (56%), having to learn how to do the test (40%), discomfort with stool collection (32%), needing a private place to perform the test (29%), and having to do MT-sDNA every 3 years (27%). Fewer patients reported having a stool sample in their home (26%), needing a toilet with a seat cover (25%), embarrassment (18%), or time (14%) as barriers. Of note, for each barrier queried, around 15% to 30% responded that they did not know how that barrier would affect their choice to be screened by MT-sDNA, reflecting an overall unfamiliarity

with MT-sDNA. Men and women did not differ significantly in their reported MT-sDNA barriers.

Patient Comparison of Colonoscopy and MT-sDNA

There was no significant difference between colonoscopy and MT-sDNA in patient-reported embarrassment, discomfort, or time to do the test. After learning about MT-sDNA and colonoscopy, over half (58%) of respondents said they would prefer colonoscopy for CRC screening, while 36% said they would prefer MT-sDNA. A total of 12% said neither test, and 14% said either test or they were unsure. Unscreened patients were significantly more likely to state a preference for MT-sDNA than previously screened patients (42% vs 31%, $P < .05$). Likewise, younger patients (<60 years old) were significantly more likely to prefer MT-sDNA than older patients (40% vs 30%, $P < .05$).

Provider Characteristics

Of the 331 invited providers, 87 (26% response rate; range 16%-61%) completed the survey (Figure 1). Three-quarters (76%) were younger than 50 years, with 57% identifying as Alaska Native/American Indian. A total of 75% were women, similar to the proportion (86%) in the invited survey group.

Provider Willingness to Recommend MT-sDNA

Over two-thirds of providers (69%) thought that patients would be more likely to be screened for CRC if they could use MT-sDNA instead of colonoscopy, and 79% reported that if MT-sDNA became available at their organization they would recommend it to patients. There was no significant difference by provider sex, age (<50 vs 50+ years), or race (Alaska Native/American Indian vs White/other) in these 2 factors. Most providers reported that if MT-sDNA was available that it would be easy to distribute and implement in their practice (79%) as well as lead to CRC screening rate increases (79%). Less than a quarter (22%) reported that MT-sDNA would require more work because the test has to be performed every 3 years.

Provider Perceptions of Patient Barriers to Colonoscopy and MT-sDNA

The most common barriers that providers thought would affect their patients' choice to get a colonoscopy were fear of pain or discomfort (92%), test invasiveness (87%), travel (77%), anesthesia (72%), taking laxatives (72%), and dependent care (66%). The barriers that providers thought would least affect their patients' choice to have a colonoscopy were embarrassment (58%) and taking too much time (48%).

The top 5 provider-reported patient barriers to MT-sDNA were stool collection (67%), stool sample in the home (63%), belief that colonoscopy better at preventing cancer (56%), learning how to do the test (56%), and embarrassment (47%). Fewer providers reported needing a toilet with a seat cover (33%), a private place to do the test (32%), testing every 3 years (22%), or time (16%) as MT-sDNA barriers to patients.

Differences in Patient and Provider Assessment of Barriers

One notable finding was the difference between patients and providers in the magnitude and ranking of barriers to colonoscopy and MT-sDNA (Figure 2). Overall, patients were most likely to report travel and the bowel preparation as primary barriers to colonoscopy, while providers thought that fear of pain and test invasiveness were the primary barriers for their patients. For MT-sDNA, patients' belief that colonoscopy was a better test and not knowing how to do the test were primary barriers, while providers thought that stool collection and having the sample in the patient's house were the primary barriers for their patients. These differences were statically significant ($P < .05$). There was also a significant difference ($P < .05$) between patients and providers in concern over anesthesia (29% vs 72%), dependent care (22% vs 66%), and whether the colonoscopy would make them feel embarrassed (18% vs 57%) or take too much time (16% vs 48%).

Discussion

This study found that MT-sDNA has potential acceptability among AN people and their health care providers. Both groups reported a willingness to use MT-sDNA and did not perceive major barriers to its use. Even though it is not yet available in the Alaska Tribal Health System, over one-third (36%) of patients said they would prefer MT-sDNA for CRC screening instead of colonoscopy, similar to another study of minority populations (Black and Latino primary care patients), which found that 31% preferred MT-sDNA.[36] The proportion of those who preferred MT-sDNA to colonoscopy was higher among unscreened and younger patients, which has important implications for improving screening uptake. Providers were likewise open to MT-sDNA, the majority of whom indicated they would use MT-sDNA if available and felt that it would improve CRC screening rates in this population. However, there was a lack of patient familiarity with completing MT-sDNA, provider uncertainty about its effectiveness, as well as a belief among both patients and providers that colonoscopy is better at preventing cancer. Because of the high false positive rates associated with guaiac-based fecal occult blood tests in the AN population there has been a reluctance among

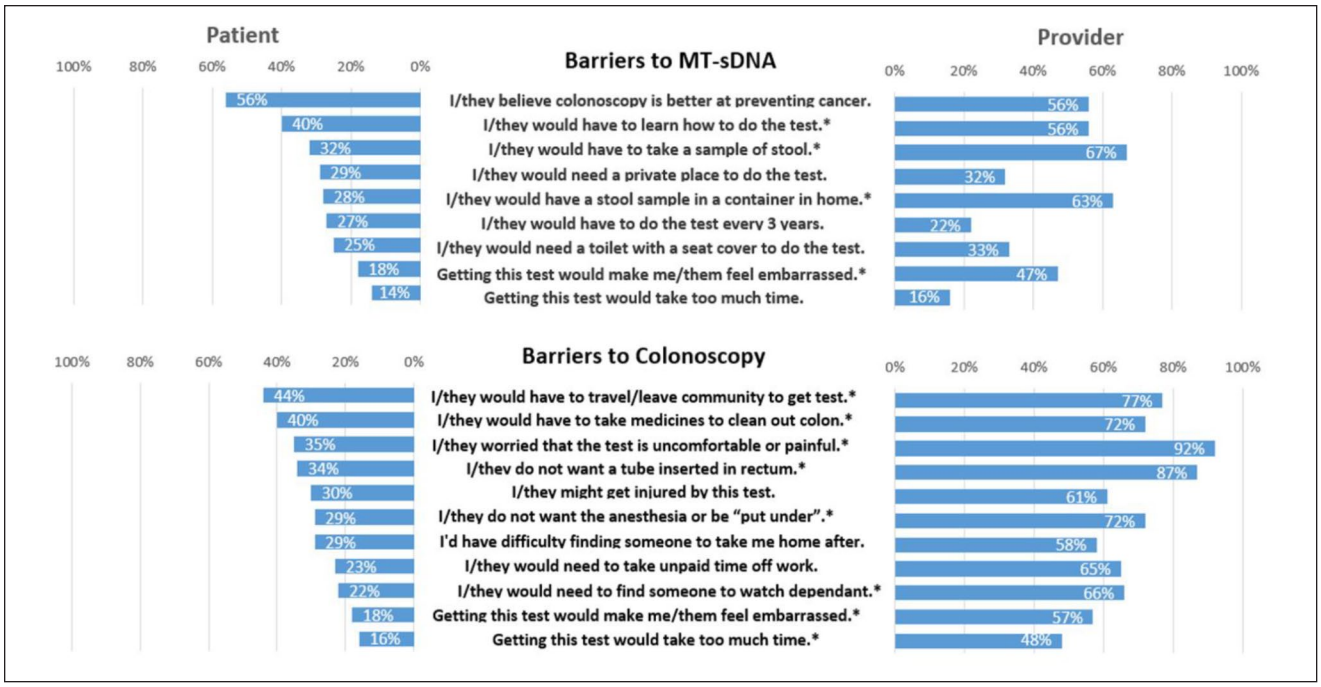

Figure 2. Differences in patient and provider assessment of barriers to multitarget stool DNA test and colonoscopy.
*Indicates statistically significant differences between patients and providers ($P < .05$).

providers to use stool tests, which makes the interest in MT-sDNA evidenced by this study more surprising.

Many factors play a role in screening adherence and test preferences.[24,37-49] Data from the National Health Interview Survey (NHIS) indicate that the most commonly reported reason (40%) for not having a CRC screening was "no reason or never thought about it,"[50] which was similar to non-screened AN respondents in the current study (46%). Other reasons for not having a CRC screening were about twice as high among AN respondents as the NHIS data.[50]

One of the most notable findings of this study was the difference in both the magnitude and ranking of barriers between patients and providers, especially for colonoscopy. Providers tended to overestimate how much pain and concern about the invasiveness of the test (colonoscopy) would affect their patient's choice to be screened. Patients were much less likely to view potential issues as barriers, and the barriers that patients noted were mostly logistic, such as travel and bowel preparation issues. A sizeable minority of patients was unaware of the need for CRC screening and did not know where to complete their screening. These data indicate gaps in public health knowledge and messaging and suggest that health care providers should continue to strongly recommend and support CRC screening among the patients that they serve.

Limitations of this study include potential selection bias. Our provider response rate (26%) was low, but similar to other surveys of providers, especially surveys that do not offer incentives.[51,52] Additionally, the provider groups included in the study were at multiple levels of practice, from community health aides to medical doctors. There may be differences in perceptions of MT-sDNA and colonoscopy by provider type that we were unable to observe. Similarly, although the patient response rate (19%) was not atypical for a mailed questionnaire study, especially in hard-to-reach populations[53,54]; patient respondents may differ from nonrespondents in their willingness to participate in a CRC screening survey. Patients may also have had low levels of literacy, which may have impeded their ability to complete the questionnaire. However, there is not an a priori reason that this would have biased our findings regarding preferences between colonoscopy and MT-sDNA. Patient respondents were similar in gender and age characteristics to the underlying Indian Health Service user population distributions in the participating Tribal health regions as well as similar in their screening status: A total of 58% patient respondents reported having been screened compared to 59% of AN people statewide who are up-to-date with CRC screening.[6]

Another potential limitation is that this was a hypothetical study of preferences. While over half of patients had been screened previously, primarily with colonoscopy, none had experience with MT-sDNA, which may have led them to over- or underestimate the relative benefits of MT-sDNA in comparison with colonoscopy. An intervention study in which patients are offered a choice of tests would help confirm these initial findings.

Multitarget stool DNA testing may represent a new strategy to expand CRC screening for AN people or other rural/remote populations and reduce both CRC incidence and mortality, especially where access to colonoscopy is limited. The results also highlight barriers to existing screening practices that can be used to identify areas for education for both patients and providers and strengthen CRC prevention and control.

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The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Two authors (DAA and JBK) have disclosed relationships with Exact Sciences.

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ORCID iD

Diana G. Redwood https://orcid.org/0000-0003-0360-5729

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