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Factors associated with inadequate colorectal cancer screening with flexible sigmoidoscopy

Adeyinka O. Laiyemo, M.D., M.P.H.[1,2], **Chyke Doubeni, M.D., M.P.H.**[3], **Paul F. Pinsky, Ph.D.**[4], **V. Paul Doria-Rose, D.V.M., Ph.D**[5], **Andrew K. Sanderson II, M.D.**[1], **Robert Bresalier, M.D.**[6], **Joel Weissfeld, M.D., M.P.H.**[7], **Robert E. Schoen, M.D., M.P.H.**[7], **Pamela M. Marcus, Ph.D.**[2], **Philip C. Prorok, Ph.D.**[2], and **Christine D. Berg, M.D.**[4]

[1]Division of Gastroenterology, Department of Medicine, Howard University College of Medicine, Washington DC [2]Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland [3]Department of Family Medicine, University of Massachusetts, Massachusetts [4]Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland [5]Health Services and Economics Branch, Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland [6]M.D. Anderson Cancer Center, Houston, Texas [7]Department of Medicine and Epidemiology, University of Pittsburgh, Pittsburgh, Pennsylvania

Abstract

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Corresponding author: Adeyinka O. Laiyemo, M.D., M.P.H., Division of Gastroenterology, Department of Medicine, Howard University College of Medicine, 2041 Georgia Avenue, NW, Washington DC 20060. Phone: (202) 865 – 7186; Fax: (202) 865 – 6562; adeyinka.laiyemo@howard.edu.
Chyke Doubeni, M.D., M.P.H., Department of Family Medicine, University of Massachusetts, 55 Lake Avenue North, Worcester, MA 01655. Phone:774-443-7772; Chyke.Doubeni@umassmed.edu
Paul F. Pinsky, Ph.D., Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd, Bethesda, MD 20892, Phone: (301) 402-6480; pinskyp@mail.nih.gov
V. Paul Doria-Rose, D.V.M., Ph.D., Health Services and Economics Branch, Division of Cancer Control and Population Sciences, National Cancer Institute, 6130 Executive Blvd, Bethesda, MD 20892. Phone: 301-496-8500 doriarop@mail.nih.gov
Andrew K. Sanderson II, M.D., Department of Medicine, Howard University College of Medicine, 2041 Georgia Avenue, NW, Washington DC 20060. Phone: (202) 865 – 7080; andrew.sanderson@howard.edu
Robert Bresalier, M.D., M.D. Anderson Cancer Center, 1400 Pressler, Unit Number: Unit 1466, Houston, TX 77030. Phone: 713-745-4340 rbresali@mdanderson.org
Joel Weissfeld, M.D., M.P.H., Department of Medicine and Epidemiology, University of Pittsburgh, 5150 Centre Avenue, Pittsburgh, PA 15232, Phone: (412) 623-3313 jwepid@pitt.edu
Robert E. Schoen, MD, MPH, Department of Medicine and Epidemiology, University of Pittsburgh, 200 Lothrop St., Pittsburgh, PA 15213, Phone: 412-648-9825 rschoen@pitt.edu
Pamela M. Marcus, PhD., Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd, Bethesda, MD 20892, Phone: (301) 496-7468; marcusp@mail.nih.gov
Philip C. Prorok, Ph.D., Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd, Bethesda, MD 20892, Phone: (301) 496-7709; prorokp@mail.nih.gov
Christine D. Berg, M.D., Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd, Bethesda, MD 20892, Phone: (301) 496-1071; bergc@mail.nih.gov

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CONFLICT OF INTEREST
We have no conflict of interest to declare

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Background and study aim—Inadequate colorectal cancer screening wastes limited endoscopic resources. We examined patients factors associated with inadequate flexible sigmoidoscopy (FSG) screening at baseline screening and repeat screening 3–5 years later in 10 geographically-dispersed screening centers participating in the ongoing Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Methods—A total of 64,554 participants (aged 55 – 74) completed baseline questionnaires and underwent FSG at baseline. Of these, 39,385 participants returned for repeat screening. We used logistic regression models to assess factors that are associated with inadequate FSG (defined as a study in which the depth of insertion of FSG was <50 cm or visual inspection was limited to <90% of the mucosal surface but without detection of a polyp or mass).

Results—Of 7,084 (11%) participants with inadequate FSG at baseline, 6,496 (91.7%) had <50 cm depth of insertion (75.3% due to patient discomfort) and 500 (7.1%) participants had adequate depth of insertion but suboptimal bowel preparation. Compared to 55–59 year age group, advancing age in 5-year increments (odds ratios (OR) from 1.08 to 1.51) and female sex (OR = 2.40; 95% confidence interval (CI): 2.27 – 2.54) were associated with inadequate FSG. Obesity (BMI >30 kg/m^2) was associated with reduced odds (OR = 0.67; 95%CI: 0.62 – 0.72). Inadequate FSG screening at baseline was associated with inadequate FSG at repeat screening (OR = 6.24; 95%CI: 5.78 – 6.75).

Conclusions—Sedation should be considered for patients with inadequate FSG or an alternative colorectal cancer screening method should be recommended.

Keywords

Flexible sigmoidoscopy; colorectal cancer; inadequate screening; colon polyp

INTRODUCTION

Flexible sigmoidoscopy (FSG) is an acceptable modality for colorectal cancer screening which allows a visual examination of the distal colorectum without the need for sedation and extensive bowel preparation. An adequate FSG requires a stool-free examination of the distal colorectal mucosa with an optimal depth of insertion so that polyps can be identified and removed. The procedure can be performed by trained nurses, general practitioners, and specialists, thereby making it potentially readily available and accessible to the population at large. FSG screening has been shown to reduce mortality from colorectal cancer (CRC) in a randomized trial (1).

However, FSG which is suboptimal in the depth of insertion (typically less than 50cm) or bowel preparation wastes patients' and providers' time and may reduce the enthusiasm for further screening (2). Furthermore, inadequate FSG has been associated with subsequent colorectal cancer (3, 4). Previous studies, largely single institution experience with relatively small numbers of patients, have suggested that older individuals and women are more likely to have inadequate FSG, but there is limited information on other factors that may be associated with inadequate FSG (5, 6).

In the present study, we sought to evaluate patients' characteristics that are associated with inadequate FSG screening in 10 geographically dispersed screening centers in the United States of America participating in the ongoing Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) and to evaluate whether inadequate FSG at baseline predicts subsequent inadequate FSG.

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METHODS

The Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO)

The rationale and design of the PLCO trial have been published (7–9). In brief, PLCO is an ongoing multicenter, randomized controlled screening trial designed to evaluate the effect of screening for prostate, lung, colorectal and ovarian cancers on mortality. A total of 154,910 participants who were 55 – 74 years old (77,449 and 77,461 participants in the intervention and control arms, respectively), were recruited from November 1993 to July 2001. The participants in the intervention arm were offered: a) digital rectal examination and serum prostate-specific antigen for prostate cancer; b) chest X-ray for lung cancer; c) CA125 measurements plus transvaginal ultrasound for ovarian cancer; and d) flexible sigmoidoscopy for colorectal cancer. The exclusion criteria included any history of prostate, lung, colorectal, or ovarian cancer, a history of treatment for a non-PLCO cancer within a year prior to recruitment, prior total colectomy and participation in another cancer screening or primary prevention study.

Unlike the randomized, controlled trials of flexible sigmoidoscopy in the United Kingdom (10), Norway (11), and Italy (12), which involved a single screening FSG, the PLCO is evaluating two screening FSG examinations. The initial interval between the examinations was 3 years, but the protocol was revised and the interval was changed to 5 years in 1995. The PLCO protocol discouraged repeat FSG screening in persons with colorectal cancer or adenoma diagnosed after baseline FSG since these individuals are expected to be under appropriate colonoscopic surveillance.

Beginning in April 15, 1995, the PLCO trial did not enroll any new subjects reporting a proctoscopy, sigmoidoscopy, barium enema, or colonoscopy within the previous 3 years. Of the 77,449 participants in the intervention arm, 64,973 (83.9%) were randomized after April 15, 1995. The participants in the intervention arm were offered screening FSG at baseline at ten screening centers across the United States (Minneapolis, MN; Pittsburgh, PA; Salt Lake City, UT; St. Louis, MO; Birmingham, AL; Denver, CO; Detroit, MI; Honolulu, HI; Marshfield, WI; and Washington, DC). The study was approved by the National Cancer Institute and the Institutional Review Boards at each of the screening centers. All participants gave written informed consent.

Exposure and outcome assessment

Information on each participant’s demographic characteristics, lifestyle factors, personal and family medical history was obtained by means of a self-administered questionnaire at baseline. The PLCO protocol required that all examiners, except board-certified gastroenterologists or physicians with hospital privileges to perform FSG or colonoscopy, undergo training and certification by PLCO staff. The examiners were recruited from various clinical backgrounds (physicians, registered nurses, nurse practitioners, and physician assistants). The examiners watched a videotape and observed 10 procedures. The examiners then performed 10 practice procedures followed by a minimum of 25 successful procedures under the guidance of a trained gastroenterologist.

The goal of the FSG screening is to achieve a technically adequate examination defined as accomplishing at least a 50 cm depth of insertion of the FSG with adequate visualization of at least 90% of the colorectal mucosa. The examiners used depth of insertion, adequacy of bowel preparation, and primary visual findings to place each sigmoidoscopy examination into one of four mutually exclusive result categories: a) the abnormal suspicious category signified any finding of polyp or mass regardless of the depth of insertion or the degree of bowel preparation; b) the incidental abnormal category signified any abnormality other than mass or polyp, such as hemorrhoids or diverticuli during an adequate FSG examination; c)

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the inadequate FSG category signified less than 50 cm depth of insertion or visual inspection less than 90% of the mucosal surface due to inadequate bowel preparation, without detection of polyp or mass; and d) the normal result category signified a technically adequate examination without polyp, mass, or any other incidental abnormality. A total of 64,554 participants who completed the baseline questionnaire and underwent baseline FSG are the focus of the current analysis. Per the protocol of PLCO, any patient with an abnormal FSG revealing a polyp or mass is to undergo diagnostic colonoscopy which is expected to be completed within 1 year of the abnormal FSG. These patients are expected to undergo subsequent surveillance colonoscopy as appropriate based on the findings and were not expected to undergo repeat FSG. Of 49,359 participants included in this study who were expected for repeat FSG screening 3–5 years later, 39,385 (79.8%) returned for their procedures.

Statistical analyses

We used Statistical Analysis Systems (SAS) software version 9.1.3 (SAS Institute Inc, Cary, NC) for all analyses. We compared the characteristics of participants by whether the screening FSG was inadequate or not at baseline and at repeat FSG screening. We used chi-square tests for categorical variables and Student t – test for continuous variables. We explored the reasons for inadequate FSG and used unconditional logistic regression models to assess factors that were associated with inadequate FSG, both at baseline screening and at repeat FSG. Our final model included age, sex, education, smoking status, race-ethnicity, body mass index, and screening center. We included whether the baseline FSG was inadequate or not in the model evaluating factors associated with inadequate FSG at repeat examination 3–5 years after baseline FSG. We calculated odds ratios (OR) with 95% confidence intervals (CI) and the alpha error was set at 0.05 level.

RESULTS

A total of 64,554 participants completed the baseline questionnaires and underwent baseline FSG. The mean age of the participants was 63 years, 51.1% were male, the mean BMI was 27.3 kg/m^2 and 10.6% had a first-degree relative with CRC. A total of 57,470 (89%) participants had adequate FSG examination while 7,084 (11%) participants had inadequate FSG at baseline. Of 49,359 participants included in this study who were expected for repeat FSG screening 3–5 years later, 39,385 (79.8%) returned for their procedures. When compared to those with adequate baseline FSG who were expected for repeat screening, participants with inadequate FSG at baseline were less likely to return for repeat screening overall (65.3% versus 81.6%; P value <0.001). When analyzed by the expected time to return for repeat FSG, of participants expected for a FSG in year 3, 80.8% returned (82.4% with adequate and 67.7% with inadequate baseline FSG). Of participants expected for a repeat FSG at year 5, 79.4% returned (81.3% with adequate and 64.3% with inadequate baseline FSG).

A total of 5,021 (12.7%) participants had inadequate FSG at repeat screening 3–5 years after the baseline examination. Table 1 displays reasons for inadequate FSG at baseline and at repeat FSG 3–5 years later. The depth of insertion was not recorded for 21 (0.3%) and 6 (0.1%) participants at baseline and repeat FSG, respectively. At baseline, of 6,496 participants with less than 50 cm depth of insertion, 4,889 (75.3%) reported patient discomfort. Of the 567 participants with adequate depth of insertion, 500 (88.2%) were due to poor bowel preparation. Of the 5,015 participants with inadequate FSG at repeat screening with known depth of insertion of the sigmoidoscope, 4,509 (89.9%) had less than 50 cm depth of insertion and participant discomfort was associated with 3,275 (72.6%) inadequate procedures. The mean length of insertion of sigmoidoscope for participants with less than 50cm of insertion was 34.9 cm at baseline and 35.4 cm at repeat FSG. Suboptimal

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bowel preparation was documented for 1,759 (35.0%) inadequate FSG at repeat examination, of whom 469 (26.7%) had adequate depth of insertion.

When compared to those with adequate FSG at baseline, participants with an inadequate examination were older (mean age 63.6 versus 63.0 years; P value <0.001) and had lower mean BMI (26.7 versus 27.4 kg/m^2; P value <0.001). However, there was no difference in the proportion of participants with a first degree relative with a history of CRC (10.7% versus 10.6%; P value = 0.935). We found a similar pattern among participants who underwent repeat FSG 3–5 years after the baseline examination (data not shown).

In our fully adjusted model for baseline FSG, advancing age in 5-year increment from age 60 was associated with significantly increased odds of inadequate FSG with odds ratios (OR) ranging from 1.08 to 1.51 (Table 2). Female sex and history of smoking particularly current smoking were also associated with inadequate FSG. Advanced education, overweight (BMI 25– 29 kg/m^2) and obesity (BMI > 30 kg/m^2) were associated with reduced odds. At repeat FSG 3–5 years later, a similar pattern was observed except that cigarette smoking was not significantly associated with increased odds of inadequate FSG (Table 3). However, the strongest predictor of inadequate FSG at repeat screening was inadequate baseline FSG (OR = 6.24; 95% CI: 5.77 – 6.75). An astonishing 44% of those with inadequate FSG at baseline had inadequate FSG at repeat examination 3–5 years later.

DISCUSSION

We examined factors that were associated with inadequate FSG in 10 geographically dispersed screening centers in the PLCO, an ongoing randomized control trial evaluating whether FSG can reduce mortality from CRC. We observed a positive association between advancing age, female sex and smoking with inadequate FSG at baseline. Higher educational status and BMI were associated with reduced odds of inadequate FSG. The majority of inadequate FSG were due to patients' discomfort. Unlike other FSG trials (10–12), participants in PLCO were offered two FSG as part of the screening program which provided us the opportunity to evaluate inadequate screening FSG at two time points. We had previously reported that participants with inadequate FSG were less likely to return for repeat screening at 3 years (2). The present study demonstrates that the same holds whether participants were due to return either 3 or 5 years later. Most importantly, the strongest predictor of inadequate FSG at repeat screening was inadequate baseline screening. We observed that 44% of those with inadequate baseline FSG had inadequate FSG at repeat screening 3–5 years later. Therefore, we recommend that once a patient has an inadequate FSG particularly due to patient discomfort, sedation should be considered or an alternate modality for colorectal screening should probably be recommended. This may be important when scheduling a repeat screening examination following an incomplete FSG even in a once-only FSG screening scenario.

We are not aware of any study that has evaluated adequacy of repeat endoscopy in a longitudinal follow-up among patients with previous inadequate endoscopic screening for a direct comparison with our study. Nonetheless, our baseline inadequate FSG findings are comparable to previously published studies. In a study involving 3,980 subjects who underwent FSG screening in a single center, Eloubeidi et al. (5) reported that females (OR = 1.83; 95% CI: 1.60–2.10) and advancing age per year increase (OR = 1.02; 95% CI: 1.01–1.03) were associated with inadequate FSG examinations. Similarly, Doria-Rose et al. (4) evaluated the likelihood of having an inadequate FSG defined as depth of insertion less than 40 cm. The authors reported that advancing age was associated with increased risk of inadequate FSG and also reported a two-fold increased risk of inadequate FSG among women (RR = 2.3; 95% CI 2.2–2.5). Furthermore, Ramakrishnan et al. (6) reported

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increased odds of incomplete depth of insertion with advancing age and 75% of the inadequate FSG occurred in women.

Chou et al. (13) reported that body mass index (BMI) < 25 kg/m2 (OR = 1.41; 95% CI: 1.05 – 1.89) was an independent risk factors for incomplete FSG among adult Chinese in Taiwan. We are not aware of any study that has evaluated the association of obesity (BMI ≥ 30 kg/m^2) with inadequate FSG. BMI less than 25 kg/m^2 has also been reported to be associated with difficult colonoscopy (14, 15). Chung et al. (15) also reported increased odds of painful unsedated colonoscopy among Korean patients with BMI< 23 kg/m^2 (OR 1.65; 95% CI 1.08–2.51). These reports are consistent with our findings. In contrast, Borg et al. (16) reported that BMI ≥ 25 kg/m^2 was an independent risk factor for an inadequate bowel preparation at colonoscopy. We observed that overweight and obese individuals were more likely to have adequate depth of insertion and optimal visualization of the colonic mucosa during FSG. The exact mechanism of this finding is unclear, but we suspect that sharp angulations are less prevalent in more obese subjects.

A strength of our study is that we prospectively examined factors associated with inadequate FSG in a large geographically dispersed cohort. In addition, all the information was prospectively collected. The FSG were performed by endoscopists of different specialties and training which enables our study to mirror what may occur in real world scenario when non physicians and physicians perform FSG to increase the capacity for CRC screening. We have previously reported that nurse practitioners and gastroenterologists had comparable performance of adequate FSG examinations and there were no meaningful differences in adenoma detection by examiner specialty (17). However, our study has limitations. Endoscopists determined depth of insertion not by fluoroscopy or the use of a computer aided system; instead they assumed straightness of the scope, which may not accurately represent true depth of insertion.

In conclusion, we observed inadequate examination in approximately one tenth of participants who underwent FSG as part of PLCO screening; inadequacy was associated with advancing age and female sex. Participants with inadequate FSG screening at baseline were less likely to return for repeat FSG, underscoring the importance of performing a high quality screening at the first attempt. Furthermore, those with inadequate baseline FSG were more likely to have repeated inadequate FSG. This suggests that after an inadequate FSG, sedation should be considered at repeat examination or the patient should be offered a different modality for CRC screening especially in light of reports suggesting that inadequate FSG is associated with subsequent colorectal cancer (3, 4).

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Table 1

Reasons for inadequate flexible sigmoidoscopy (FSG) screening by depth of insertion [a]

	Baseline FSG [b]		Repeat FSG in 3–5 years [c]	
Reason	**Depth of insertion, n (%)**		**Depth of insertion, n (%)**	
	< 50 cm	**≥ 50 cm**	**< 50 cm**	**≥ 50 cm**
All	6,496 (100)	567 (100)	4509 (100)	506 (100)
Severe ulcerative colitis	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Participant discomfort	4889 (75.3)	35 (6.2)	3243 (71.9)	32 (6.3)
Severe diverticulosis with unclear lumen	534 (8.2)	17 (3.0)	317 (7.0)	11 (2.2)
Equipment malfunction	20 (0.3)	4 (0.7)	11 (0.2)	3 (0.6)
Poor bowel preparation	1485 (22.9)	500 (88.2)	1290 (28.6)	469 (92.7)
Participant refusal	337 (5.2)	2 (0.4)	232 (5.1)	1 (0.2)
Vasovagal response	99 (1.5)	3 (0.5)	21 (0.5)	3 (0.6)
Palpitations with tachycardia	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0).

[a] Reasons for inadequate examinations were not mutually exclusive

[b] At baseline, depth of insertion was missing for 21 participants. The specific reason for inadequate FSG designation for 6 participants with depth of insertion of 50 cm or more was missing.

[c] At repeat FSG, depth of insertion of the flexible sigmoidoscope was missing for 6 participants

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Table 2

Risk factors for inadequate baseline flexible sigmoidoscopy [a]

Characteristics	All subjects N	Adequate examination n	Inadequate examination n	Proportion with inadequate examination (95% CI)	OR (95% CI)
Age group in years					
55–59	21696	19497	2199	0.10 (0.10, 0.11)	1.0 (reference)
60–64	20015	17963	2052	0.10 (0.10, 0.11)	1.08 (1.01, 1.15)
65–69	14506	12806	1700	0.12 (0.11, 0.12)	1.27 (1.19, 1.36)
70–74	8337	7204	1133	0.14 (0.13, 0.14)	1.51 (1.39, 1.63)
Male	32992	30699	2293	0.07 (0.07, 0.07)	1.0 (reference)
Female	31562	26771	4791	0.15 (0.15, 0.16)	2.40 (2.27, 2.54)
Highest education attained					
High School or Less	27057	23861	3196	0.12 (0.11, 0.12)	1.0 (reference)
Some/Graduated College	25265	22546	2719	0.11 (0.10, 0.11)	0.94 (0.89, 0.99)
Postgraduate	12158	10996	1162	0.10 (0.10, 0.10)	0.91 (0.84, 0.98)
Smoking status					
Never	30187	26760	3427	0.11 (0.11, 0.12)	1.0 (reference)
Former	27854	24987	2867	0.10 (0.10, 0.11)	1.06 (1.00, 1.12)
Current	6494	5708	786	0.12 (0.11, 0.13)	1.16 (1.07, 1.27)
White, non-Hispanic	57616	51090	6526	0.11 (0.11, 0.12)	1.0 (reference)
Black, non-Hispanic	3020	2672	348	0.12 (0.10, 0.13)	0.89 (0.79, 1.00)
Hispanic	1120	996	124	0.11 (0.10, 0.13)	1.15 (0.95, 1.40)
Asian	2309	2255	54	0.02 (0.02, 0.03)	0.69 (0.50, 0.93)
American Indians/Pacific Islanders	463	434	29	0.06 (0.04, 0.09)	1.29 (0.87, 1.93)
Body mass index, kg/m^2					
≤25	21199	18373	2826	0.13 (0.13, 0.14)	1.0 (reference)
25–29	27287	24514	2773	0.10 (0.10, 0.11)	0.83 (0.78, 0.88)
≥30	15449	14030	1419	0.10 (0.09, 0.10)	0.67 (0.62, 0.72)

[a]Model included all the variables in the table and screening center

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Table 3

Risk factors for inadequate repeat flexible sigmoidoscopy [a]

Characteristics	All subjects N	Adequate examination n	Inadequate examination n	Proportion with inadequate examination (95% CI)	OR (95% CI)
Adequate baseline FSG	35834	32390	3444	0.10 (0.09, 0.10)	1.0 (reference)
Inadequate baseline FSG	3551	1974	1577	0.44 (0.43, 0.46)	6.24 (5.77, 6.75)
Age group in years					
55–59	13097	11599	1498	0.11 (0.11, 0.12)	1.0 (reference)
60–64	12618	11123	1495	0.12 (0.11, 0.12)	1.06 (0.98, 1.15)
65–69	8843	7590	1253	0.14 (0.14, 0.15)	1.31 (1.20, 1.43)
70–74	4827	4052	775	0.16 (0.15, 0.17)	1.53 (1.38, 1.70)
Male	21803	19888	1915	0.08 (0.08, 0.09)	1.0 (reference)
Female	17582	14476	3106	0.18 (0.17, 0.18)	2.16 (2.02, 2.31)
High School or Less	16009	13731	2278	0.14 (0.14, 0.15)	1.0 (reference)
Some/Graduated College	15488	13570	1918	0.12 (0.12, 0.13)	0.94 (0.88, 1.01)
Postgraduate	7840	7021	819	0.11 (0.10, 0.11)	0.88 (0.80, 0.97)
Smoking status					
Never	19293	16764	2529	0.13 (0.13, 0.14)	1.0 (reference)
Former	16892	14822	2070	0.12 (0.12, 0.13)	1.05 (0.98, 1.12)
Current	3189	2769	420	0.13 (0.12, 0.14)	1.05 (0.93, 1.18)
White, non-Hispanic	35131	30458	4673	0.13 (0.13, 0.14)	1.0 (reference)
Black, non-Hispanic	1629	1431	198	0.12 (0.11, 0.14)	0.95 (0.80, 1.13)
Hispanic	663	575	88	0.13 (0.11, 0.16)	1.31 (1.03, 1.68)
Asian	1653	1609	44	0.03 (0.02, 0.04)	0.91 (0.63, 1.32)
American Indians/Pacific Islanders	294	276	18	0.06 (0.04, 0.10)	1.34 (0.79, 2.27)
Body mass index, kg/m^2					
≤25	12848	10978	1870	0.15 (0.14, 0.15)	1.0 (reference)
25–29	17213	15109	2104	0.12 (0.12, 0.13)	0.92 (0.85, 0.98)
≥30	8961	7962	999	0.11 (0.11, 0.12)	0.79 (0.72, 0.86)

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[a]Model included all the variables in the table and screening center