

Development and Validation of a Scoring System to Identify Individuals at High Risk for Advanced Colorectal Neoplasms Who Should Undergo Colonoscopy Screening

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BACKGROUND & AIMS: Screening the population for colorectal cancer (CRC) by colonoscopy could reduce the disease burden. However, targeted screening of individuals at high risk could increase its cost effectiveness.

METHODS: We developed a scoring system to identify individuals with at least 1 advanced adenoma, based on easy-to-collect risk factors among 7891 participants of the German screening colonoscopy program. The system was validated in an independent sample of 3519 participants. Multiple logistic regression was used to develop the algorithm, and the regression coefficient-based scores were used to determine individual risks. Relative risk and numbers of colonoscopies needed for detecting one or more advanced neoplasm(s) were calculated for quintiles of the risk score. The predictive ability of the scoring system was quantified by the area under the curve.

RESULTS: We identified 9 risk factors (sex, age, first-degree relatives with a history of CRC, cigarette smoking, alcohol consumption, red meat consumption, ever regular use [at least 2 times/wk for at least 1 y] of nonsteroidal anti-inflammatory drugs, previous colonoscopy, and previous detection of polyps) that were associated significantly with risk of advanced neoplasms. The developed score was associated strongly with the presence of advanced neoplasms. In the validation sample, individuals in the highest quintile of scores had a relative risk for advanced neoplasm of 3.86 (95% confidence interval, 2.71–5.49), compared with individuals in the lowest quintile. The number needed to screen to detect 1 or more advanced neoplasm(s) varied from 20 to 5 between quintiles of the risk score. In the validation sample, the scoring system identified patients with CRC or any advanced neoplasm with area under the curve values of 0.68 and 0.66, respectively.

CONCLUSIONS: We developed a scoring system, based on easy-to-collect risk factors, to identify individuals most likely to have advanced neoplasms. This system might be used to stratify individuals for CRC screening.

Keywords: Colorectal Neoplasm; Prediction; Screening; Average-Risk Population.

See related article, Brenner H et al, on page 709 of *Gastroenterology*.

Colorectal cancer (CRC) is the third most common cancer worldwide, accounting for more than 1.2 million new cases and more than 600,000 deaths annually.¹ Because of its slow progression from detectable precancerous lesions and the much better prognosis of patients diagnosed at early stages, the potential for reducing the burden of the disease by early detection is large. A number of screening tests have been developed and found to be effective in randomized^{2–4} and observational^{5–7} studies.

The most reliable method for early detection of precancerous lesions and early CRC is colonoscopy,^{8,9} which

has been introduced as a primary screening offer in a number of countries in recent years, even though its effects on reducing CRC incidence and mortality have not been shown in a randomized clinical trial so far. A major disadvantage of colonoscopy is its invasive nature, which goes along with higher discomfort, lower compliance, higher costs, and higher complication rates, compared with other screening methods. In the majority of people

Abbreviations used in this paper: AUC, area under the operating characteristic curve; BliTz, Begleitende Evaluierung innovativer Testverfahren zur Darmkrebsfrüherkennung; BMI, body mass index; CRC, colorectal cancer; NSAID, nonsteroidal anti-inflammatory drug.

undergoing colonoscopy, no clinically relevant colorectal neoplasm is found, and colonoscopy does not offer any true prevention to those participants. Simple tools for risk stratification therefore might be useful, which enable more targeted offers of screening colonoscopy to people at high risk of clinically relevant colorectal neoplasms who most likely will benefit from the procedure, and of other, less-invasive screening procedures to those at lower risk.

Risk prediction algorithms based on demographic and risk factor information could be useful tools for such risk stratification. In recent years, such algorithms have been developed and applied to a number of cancers including CRC.¹⁰⁻¹⁴ However, existing CRC risk scores mostly have been derived in clinical settings for clinically manifest CRC, whereas the main target for CRC screening and prevention is preclinical CRC and its precursors.

We aimed to develop and validate a scoring system to identify individuals at high risk for advanced colorectal neoplasms among the average-risk population for CRC screening based on some easy-to-collect risk factors.

Methods

Study Design and Study Population

Our study was performed among participants of the German screening colonoscopy program by linking self-reported information on CRC risk factors with findings at colonoscopy. Detailed information on the German screening colonoscopy program has been provided elsewhere.¹⁵ Briefly, colonoscopy was offered as a primary screening examination free of charge to the whole residents aged 55 years and older in Germany since 2002. Screening colonoscopy is conducted almost exclusively in practices of gastroenterology or internal medicine. Only very experienced endoscopists are entitled to provide screening colonoscopies, which are subject to rigorous quality control.

The study population for this analysis included 2 samples taken from 2 ongoing studies among participants of the German screening colonoscopy program. These subgroups, described in detail later, served as a derivation group and a validation group. Advanced colorectal neoplasms include CRC as well as advanced colorectal adenomas, which are defined as adenomas with at least one of the following features: 1 cm or larger in size, tubulovillous or villous components, or high-grade dysplasia.

Derivation Sample

The derivation subgroup consisted of screening colonoscopy participants recruited between 2005 and 2009 in the context of the Effektivität der Früherkennungs-Koloskopie: Eine Saarland-weite Studie, which is an ongoing cohort study initiated with the primary aim of monitoring long-term reduction of CRC incidence and mortality among participants of screening

colonoscopy.^{16,17} Almost all (n = 33) gastroenterology practices contribute to recruitment in this statewide study conducted in Saarland, a small state with approximately 1 million inhabitants located in southwest Germany. The Effektivität der Früherkennungs-Koloskopie: Eine Saarland-weite Studie was approved by the ethics committees of the University of Heidelberg and of the state medical chamber of Saarland.

Validation Sample

The validation study consisted of screening colonoscopy participants recruited between 2005 and 2011 in the context of the Begleitende Evaluierung innovativer Testverfahren zur Darmkrebsfrüherkennung (BliTz) study, which was initiated with the primary aim of validating new blood and stool tests for noninvasive CRC screening.¹⁸⁻²² Recruitment was performed in 20 gastroenterology practices in southern Germany. The BliTz study was approved by the ethics committee of the University of Heidelberg and of the state medical chambers of Baden-Württemberg, Rheinland Pfalz, and Hessen.

Data Collection

In both studies, participants were asked to complete a standardized questionnaire, which included information on sociodemographic factors, personal and family medical history of CRC, and other diseases. Furthermore, a lifetime history of smoking as well as information on alcohol consumption, dietary habits, and physical activity within the past 12 months preceding colonoscopy was collected.

After colonoscopy, colonoscopy and histology reports were collected from all participants in both studies. Relevant information was extracted by 2 trained research assistants independently who were not aware of the questionnaire data. Data entries were controlled for inconsistencies, and any discrepancies were resolved by a recheck of the records.

Definitions of Predictors

We assessed a variety of well-established risk factors for CRC as potential predictors of the presence of at least one advanced neoplasm.^{10,13,14} Based on the self-administered questionnaire, the following variables were included: sex, age (in years), body mass index (BMI, kg/m²), number of first-degree relatives with a history of CRC, number of pack-years of current and former smokers, average alcohol consumption in the past 12 months (grams ethanol per week), ever regular use (at least 2 times/week for at least 1 year) of nonsteroidal anti-inflammatory drugs (NSAIDs) including aspirin (yes/no), average physical activity in the past 12 months based on specific metabolic equivalent scores according to the compendium of physical activities provided by Craig et al²³ (metabolic equivalent hours/week), previous colonoscopy (yes/no), findings of polyps at a

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