

ORIGINAL ARTICLE

Should Screening Colonoscopy Be Offered From Age 50?

Results From a Statewide Pilot Project, and From a Randomized Intervention Study

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SUMMARY

Background: The introduction of colonoscopic screening in 2002 for persons aged 55 and older was followed by a marked decline in the incidence of colon cancer in the corresponding age groups in Germany. The prevalence of colorectal neoplasia among persons aged 50 to 54 has remained unknown until now. Expert committees currently recommend colonoscopic screening for persons aged 50 and older. This option has been offered since 2014 by the AOK Baden–Württemberg and by Bosch BKK in the framework of their specialized medical care program.

Methods: In April 2014 and 2015, 84 726 insurees aged 50–54 were invited by mail to participate in colonoscopic screening. The utilization and results of colonoscopic screening were studied. A questionnaire about risks was additionally sent to half of the participants, who were selected at random (study registration: DRKS00006268).

Results: Within one year, 1.9% of persons to whom invitations had been sent took up the offer of colonoscopic screening; these persons included 3.3% of those already enrolled in the specialized medical care program. The 1396 colonoscopies that were performed revealed advanced neoplasia (colon cancer or advanced adenoma) in 6.8% of cases. The prevalence of advanced neoplasia among men aged 50 to 54 was nearly twice as high as that among women in the same age group (8.6% vs. 4.5%, $p = 0.0027$). It was also higher than the prevalences documented in the German nationwide cancer registry for women aged 55 to 79. The additional sending of a risk questionnaire along with the invitation had no effect on the rate of detection of relevant findings or on the rate of participation in colonoscopic screening.

Conclusion: These findings lend support to the demand that the offer of colonoscopic screening should be extended at least to men aged 50 and above.

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Despite the decline in incidence observed in recent years, colorectal cancer remains the third most common cancer in Germany with more than 60 000 new cases per year. The lifetime risks for men and women are 7% and 5.7%, respectively (1). Since colorectal cancer is slow to develop over time, in most cases over many years, and the significant impact of the stage of the disease at diagnosis on its prognosis (2), the potential of screening to reduce incidence and mortality is significantly greater for colorectal cancer than for other types of cancer. Screening methods recommended by national and international expert panels include fecal occult blood tests (FOBT), sigmoidoscopy and colonoscopy (3, 4). Several randomized studies have consistently demonstrated a reduction in colorectal cancer incidence and mortality associated with screening FOBT and sigmoidoscopy (5–10). Long-term results of randomized screening colonoscopy studies are not available as yet. However, a meta-analysis of epidemiological studies, including a study from Germany (11), indicates that a screening colonoscopy during which precursors of colorectal cancer are detected and immediately removed is associated with a two-third reduction in colorectal cancer incidence and mortality over the next 10 years (12).

Screening colonoscopy was added to the German national statutory cancer screening program in October 2002. Since then, men and women from age 55 years onwards have been entitled to a screening colonoscopy which can be repeated after 10 years if the first one was performed prior to age 65 years. With regard to the uptake and the results of screening colonoscopy, a globally unique data resource is available, based on information from a national registry, allowing detailed analyses of the opportunities and risks associated with this preventive measure (13–15). According to a model calculation, the detection and removal of colorectal adenomas in approximately 1 million participants of the screening program has prevented approximately 180 000 colorectal cancer cases in Germany during the first 10 years of the program's existence (16). Complications, such as hemorrhage (0.3%) and perforations (0.08%), are very rare (17). Even though a large proportion of the prevented new cases would only have occurred in later years (18), a significant decline in

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colorectal cancer incidence has been noted during the first 10 years of the screening colonoscopy program. This decline is selectively observed in the age groups from 55 years onwards (19).

The risk of colorectal cancer rises steeply with increasing age; prior to age 50 years, the disease rarely occurs in individuals not belonging to special high-risk groups. However, with approximately 10% of colorectal cancer cases occurring in individuals younger than 55 years, national and international professional societies have recommended to start screening colonoscopy from age 50 years (3, 4). Consequently, since April 2014 the statutory health insurance AOK Baden–Württemberg and the company health insurance Bosch BKK, in collaboration with professional organizations and scientifically supported by the German Cancer Research Center (DKFZ), have been offering screening colonoscopy starting at age 50 years, in a selective agreement on specialist care in gastroenterology pursuant to section 73c, Social Insurance Code (SGB V (old version)).

In our study, we assessed the uptake of this colorectal screening offer—overall and subject to the type and extent of the invitation letter—and the so far unknown prevalence of colorectal neoplasia in the target age group of the 50- to 54-year-olds.

Methods

Screening offer, participants and evaluation concept

The offer of AOK Baden–Württemberg and Bosch BKK to provide a screening colonoscopy from age 50 years is valid for insured persons enrolled in both the family physician program and the specialist program of the respective health insurance. As part of the family physician programs, insured persons select a family physician of their choice as a first contact. This family physician then coordinates all steps of the treatment. Participants in a family physician program can choose to additionally enroll in the special outpatient specialist care program (the “specialist program”) which requires the referral of the chosen family physician for any specialist consultation. Apart from superior treatment coordination, insured persons enrolled in both the family physician program and the specialist program enjoy further benefits as well as access to special screening and care offers, including earlier eligibility for a screening colonoscopy from age 50 years.

In April 2014 and April 2015, altogether 84 726 insured persons enrolled in the family physician program of AOK Baden–Württemberg, aged between 50 and 54 years and with no previous curative or preventive colonoscopy and no diagnosis of cancer, received one personal letter, inviting them to undergo a screening colonoscopy. In April 2015, the letter was only sent to those insured persons who had meanwhile turned 50 or had newly enrolled in the family physician program. As a prerequisite for taking up the offer, those only enrolled in the family physician program had first to join the specialist program as well. In the analysis presented here, we included all screening colonoscopies

undergone by insured persons within one year after mailing of the invitation letter and performed by a physician covered under the Gastroenterology Specialist Agreement.

In addition to the invitation letter, 50% of persons to whom an invitation letter was sent were randomly selected to be mailed a brief 1-minute questionnaire with six questions, intended to make the participant aware of an increased colorectal cancer risk associated with the presence of one or more of the following risk factors:

- Male sex
- Familial predisposition
- Smoking
- Excessive alcohol consumption
- Physical inactivity
- Obesity.

In the invitation letter sent to those participants who received the additional risk-check questionnaire, the importance of colorectal screening in case of increased risks was highlighted. The aim of the randomized study embedded in this survey was to evaluate whether such a personal risk check was associated with a higher rate of detection (primary endpoint) of target lesions (cancer or adenoma) due to the targeted use of the screening offer by high-risk groups. The secondary endpoints comprised the number of persons participating in the survey who took up the screening offer and the prevalence rates of the various lesions detected.

To be able to evaluate screening colonoscopy results among the 50- to 54-year-olds, besides determining the participation rate, the use of a standardized survey form for result documentation was made a requirement for the billing of screening colonoscopies. This form was almost identical with the one used in Germany for the nationwide documentation of screening colonoscopies from age 55 years onwards. The data entered on the form were electronically captured by the billing entity, Mediverbund AG, and, after anonymization, forwarded to the German Cancer Research Center (DKFZ) for analysis. Whether individual colonoscopy results were from an invited person assigned to the group with or without risk check was only disclosed if the participant had explicitly consented to the release of person-identifying data to Mediverbund, in addition to the colonoscopy results.

The protocol for the scientific evaluation, including the randomized study, was submitted to the ethics committee of the Medical Faculty of the University of Heidelberg for assessment and obtained a favorable opinion. The randomized study was registered at the German Registry for Clinical Trials (ID DRKS00006268).

Statistical analysis

First, a descriptive analysis of the screening colonoscopy participation rates was performed with regard to sex, followed by the differentiation of these analyses according to the time at which the invitation letter was sent (already enrolled in the specialist program: yes/no) and according to the type of invitation

TABLE 1

Participation in the screening colonoscopy program, according to status of the insured person at the time of invitation and to sex

	At the time of invitation enrolled in						Total		
	family physician program and specialist program			family physician program			Men	Women	Total
	Men	Women	Total	Men	Women	Total			
Invited	8334	7443	15 777	36 233	32 716	68 949	44 567	40 159	84 726
Participation	301	224	525	589	460	1049	890	684	1574
Percentage	3.6%	3.0%	3.3%	1.6%	1.4%	1.5%	2.0%	1.7%	1.9%
p Sex		0.035			0.019			0.0016	
p Program				<0.0001	<0.0001	<0.0001			

p Sex = p value for the difference in participation rate between men and women

p Program = p value for the difference in participation rates according to status of the insured person at the time of invitation

TABLE 2

Participation in the screening colonoscopy program according to enclosure of the risk check questionnaire in the invitation letter

	With risk check			Without risk check		
	Men	Women	Total	Men	Women	Total
Invited	22 340	20 023	42 363	22 227	20 136	42 363
Participation	437	339	776	453	345	798
Percentage	2.0%	1.7%	1.8%	2.0%	1.7%	1.9%
p Risk check				0.54	0.88	0.58

p Risk check = p value for the difference in participation rates according to risk check

letter (with/without risk check). Furthermore, a descriptive analysis of the prevalence rates of the respective most advanced lesions (colorectal cancer, advanced adenoma, non-advanced adenoma) detected during screening colonoscopy was performed. These analyses were then differentiated according to sex and type of invitation letter (with/without risk check). For comparison of the sex-specific prevalence rates in the age group from 50 to 54 years reported in this study, the corresponding prevalence rates for the age groups 55–59, 60–64, 65–69, 70–74, and 75–79 years from the National Screening Colonoscopy Registry in 2014 are also presented (15).

Data analysis was performed using the software SAS, Version 9.4. The statistical significance of differences in relative incidence between the various groups was tested using the (two-tailed) chi-square or Fisher’s exact test at a significance level of 5%.

Results

Table 1 shows the participation rates in our screening colonoscopy program according to status of the insured as well as sex, based on billing data from AOK Baden–Württemberg. The vast majority of the 50- to 54-year-old insured persons (n = 84 726) who were

sent an invitation letter were at the time of mailing only enrolled in the family physician program; only 15 777 persons (18.6%) already participated in the specialist program, a prerequisite for being eligible for a screening colonoscopy in this age group. A total of 1574 (1.9%) of those invited to participate took up the screening colonoscopy offer within one year after mailing of the invitation letter. With 3.3%, the participation rate was significantly higher in the group of insured persons already enrolled in the specialist program compared with those without prior enrolment (1.5%, p<0.0001). In both groups, the participation rate was higher in men compared with women.

As shown in Table 2, enclosing the risk check questionnaire in the invitation letter had no impact on participation rate. In particular, it did not increase the participation rate in men.

Data of the standardized survey form were available from 1396 (88.7%) of the altogether 1574 participants for further analyses. Table 3 shows the prevalence of the respective most advanced lesion detected during screening colonoscopy. Colorectal cancer, advanced adenoma and non-advanced adenoma as the most advanced finding during screening colonoscopy were detected in 4 (0.3%), 91 (6.5%) and 218 (15.6%) of the

TABLE 3

Most advanced lesion detected during screening colonoscopy according to sex

	Total* N = 1396		Men n = 794		Women n = 602		p Sex
	n	%	n	%	n	%	
Colorectal cancer	4	0.3	2	0.3	2	0.3	0.78
Advanced adenoma	91	6.5	66	8.3	25	4.2	0.0018
Non-advanced adenoma	218	15.6	147	18.5	71	11.8	0.0006
Advanced neoplasia (colorectal cancer or advanced adenoma)	95	6.8	68	8.6	27	4.5	0.0027
Neoplasia (colorectal cancer or adenoma)	313	22.4	215	27.1	98	16.3	<0.0001

p Sex = p value for sex difference in prevalence

*1396 participants (88.7%) with survey form could be allocated to risk check.

participants, respectively. The prevalence of advanced neoplasia was almost twice as high in men compared with women (8.6% vs 4.5%, $p = 0.0027$).

As shown in *Table 4*, no significant differences in the prevalence of colorectal neoplasia were found between the groups of participants with and without risk check enclosed in the invitation letter. Consequently, the risk check did not increase the rate of detection of clinically significant lesions.

The participation rate among the insured persons already enrolled in the specialist program at the time the invitation letter was sent was comparable to the nationwide participation rates among the 55- to 59-year-old eligible statutory health insurance members (*Table 5*). The prevalence of advanced neoplasia among the 50- to 54-year-old men insured with AOK Baden-Württemberg (8.6%) was also comparable with the nationwide prevalence among men in the age group 55 to 59 years (7.5%) insured with a statutory health insurance, and at the same time significantly higher compared with the nationwide prevalences among women insured with a statutory health insurance in all age groups between 55 and 79 years.

Discussion

In this pilot project of AOK Baden-Württemberg and Bosch BKK, the exclusive offer of a screening colonoscopy for 50- to 54-year-old insured persons enrolled in the specialist program was taken up to an extent comparable (women) or slightly greater (men) than that observed among 55- to 59-year-olds on a national level. Among the 50- to 54-year-old male participants, the prevalence of advanced neoplasia (8.6%) was higher compared with the prevalence among women insured with a statutory health insurance of all age groups who underwent a screening colonoscopy in Germany in 2014.

The significantly lower participation rate among insured persons not yet enrolled in the specialist program at the time the invitation letter was sent comes as no surprise, as enrolment in this program was a requirement for participation.

Nevertheless, the participation rate of 3.3% among those already enrolled in the specialist program appears, at first sight, to be low, but it must be borne in mind that individuals at average risk for colorectal cancer should undergo a screening colonoscopy once in 10 years. Consequently, the 10-year participation rate would have been a better indicator for the level of acceptance of this screening offer than the 1-year participation rate. However, due to the nature of the pilot project, this cannot be determined at present. The uptake rate of the nationwide screening colonoscopy program starting age 55 years is in the order of 20 to 30%. At first sight, even the 10-year participation rate appears to be not very high. However, the proportion of insured persons undergoing a colonoscopy during this 10-year period for other indications (e.g. in response to a positive fecal occult blood test or bowel symptoms) is at least as high as this. Thus, in Germany the 10-year colonoscopy uptake rate in the population aged 55 years and over has meanwhile reached approximately 55% (20).

Since colorectal cancer and its precursors can also be detected and removed during colonoscopies performed for other indications (typically even more frequently in the non-screening situation) (21), the majority of the population aged 50 years and older now benefits from the preventive potential of colonoscopy. This is reflected in the marked decline in colorectal cancer incidence rates observed in Germany in recent years (19).

Screening colonoscopy data on the prevalence of colorectal neoplasia among the 50- to 54-year-olds had so far not been available in Germany, because only

TABLE 4

Most advanced lesion detected during screening colonoscopy according to risk check

	Total* N = 1396		With risk check n = 690		Without risk check n = 706		p Risk check
	n	%	n	%	n	%	
Colorectal cancer	4	0.3	3	0.4	1	0.1	0.31
Advanced adenoma	91	6.5	46	6.7	45	6.4	0.82
Non-advanced adenoma	218	15.6	104	15.1	114	16.2	0.58
Advanced neoplasia (colorectal cancer or advanced adenoma)	95	6.8	49	7.1	46	6.5	0.66
Neoplasia (colorectal cancer or adenoma)	313	22.4	153	22.2	160	22.7	0.83

p Risk check = p value for difference in detection rates according to risk check
 * 1396 participants (88.7%) with survey form could be allocated to risk check.

TABLE 5

Age- and sex-specific prevalence rates of advanced colorectal neoplasia (colorectal cancer or advanced adenoma)

Source	Age (years)	1-year participation rates (%)		Prevalence of advanced neoplasia (%)	
		Men	Women	Men	Women
AOK Baden-Württemberg 2014/2015	50–54 (total)	2.0	1.7	8.6	4.5
	50–54 (SP)*	3.6	3.0		
National Screening Colonoscopy Registry 2014 (15)	55–59	3.2	3.5	7.5	4.3
	60–64	2.0	2.0	10.2	5.2
	65–69	1.9	2.0	10.9	5.8
	70–74	1.8	1.8	10.5	6.3
	75–79	1.1	0.9	11.7	7.5

* already enrolled in the specialist program (SP) at the time the invitation letter was sent

individuals aged 55 years and over are covered under the existing screening colonoscopy program. However, the age- and sex-specific prevalence patterns observed by us are in line with corresponding patterns in Austria, where screening colonoscopy is routinely offered from age 50 years onwards (22). A pilot project of the Bavarian Association of Statutory Health Insurance Physicians (KV Bayern) determined the prevalences of advanced neoplasia among the 50- to 54-year-olds who underwent colonoscopy between 2006 and 2008 because of a positive FOBT result or to investigate the cause of abnormal findings (21). However, these prevalence rates do not reflect the rates to be expected in the context of a screening colonoscopy program. The prevalence rates especially of pre-existing colorectal cancer are consistently higher among individuals with a positive FOBT result; likewise, individuals with pre-existing colorectal cancer are overrepresented in the population of patients undergoing other diagnostic colonoscopies. Nevertheless, the prevalence rates in men were consistently higher across all age groups with colonoscopies performed to evaluate positive

FOBT results or for diagnostic purposes; this is in line with our data. The prevalence rates observed among 50- to 54-year-old men also were significantly higher compared with those found in 55- to 69-year-old women.

A common measure of the costs in relation to the expected benefits of a screening test is the number needed to screen to detect a target lesion (here, an advanced neoplasia). This is calculated as the reciprocal of the prevalence rates reported here. From our data of the age group 50 to 54 years, a “number needed to screen“ (NNS) of 11.6 (95% confidence interval (CI): [9.3; 14.7]) for men and 22.2 [15.5; 32.3] for women was found. According to national data, the NNS for women, which ranges between 13.3 and 23.3 in the age groups between 55 and 79 years, is significantly higher than the NNS observed for men in the age group 50 to 54 years.

In our study, enclosing a simple personal risk check in the invitation letter (covering 6 risk factors) had no effect. Furthermore, the prevalence of neoplasms was not higher in the group with risk check compared to the

group without risk check. From this it can be concluded that the risk check did not increase the rate of target lesions detected. Further studies are needed to evaluate whether with more sophisticated risk checks (for example [23, 24]) or potentially the use of genetic risk scores (personalized prevention) better risk stratification and efficiency can be achieved.

One of the strengths of our study is that it is the first to report the colorectal neoplasia prevalence rates to be expected in a screening colonoscopy program for individuals aged 50 to 54 years as determined in a state-wide pilot project of a major health insurance in one of the most densely populated states in Germany. Based on our data, it is not possible to determine whether these findings are representative for Germany. However, in the State of Baden–Württemberg the uptake of the screening colonoscopy program for individuals aged 55 years is very close to the nationwide average (15). Consequently, at least regional peculiarities in the screening-related behavior of the participants and in the prevalence rates observed should be of little significance, if any. In contrast, selection bias due to the focus of our study on AOK-insured persons enrolled in the family physician program and specialist program cannot be ruled out.

Despite this limitation, our study shows that the prevalence of advanced neoplasia is already in 50- to 54-year-old men higher than in women of all age groups 55 years and over. Since screening colonoscopy is effective and cost-effective (if not cost-saving) in women and men aged 55 years and over (25, 26), our data indicate that this also applies at least to men in the age group 50 to 54 years. In conclusion, our results support the call to offer screening colonoscopy from age 50—at least to men.

KEY MESSAGES

- Of the 84 726 persons aged 50 to 54 years invited to undergo a screening colonoscopy, 1.9% actually took up the offer. With this, for the first time, the prevalence rates of clinically significant colorectal lesions was determined in this age group.
- With 3.3%, the participation rate was higher among persons already enrolled in the specialist program compared with those only enrolled in the family physician program at the time of invitation (1.5%; $p < 0.0001$).
- In 6.8% of the screening colonoscopies performed, advanced neoplasia (colorectal cancer or advanced adenomas) was detected. With 8.6%, the prevalence among men was almost twice as high compared with women (4.5%; $p = 0.0027$).
- The prevalence of advanced neoplasia among 50- to 54-year-old men was higher than the prevalences for women aged between 55 and 79 years documented in the nationwide Screening Colonoscopy Registry. Consequently, a general screening colonoscopy program from age 50 would be desirable, especially for men.
- Neither participation rates nor the prevalences of specific target lesions were influenced by enclosing a risk check in the invitation letter.

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Conflict of interest statement

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CLINICAL SNAPSHOT

A Woman With a Suspected Gallstone



Clinical presentation

A 94-year-old woman who was generally in good health came to the emergency room complaining of pain in the right upper abdominal quadrant radiating into the right shoulder, of one week's duration. She had suffered from gallstones for 50 years and had been referred by her primary care physician with the words, "Acute pain, suspected gallstone." On initial inspection of the unclothed patient, the emergency room physicians noted dermatomally distributed pustules and vesicles on an erythematous ground on the right side of the chest (segments T5 and T6). Severe herpes zoster was diagnosed. Laboratory testing and abdominal ultrasonography yielded no evidence of intra- or extrahepatic cholestasis, although a solitary gallstone was found (15 × 10 mm). The patient was admitted to the dermatology service for intravenous aciclovir treatment and

intense topical therapy. The diagnosis of painful conditions can be especially difficult in the elderly; this case underscores the need in this age group (as in all age groups) not only for appropriate history-taking, but also for a physical examination oriented to the patient's chief complaint.

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