High uptake of colonoscopy in first-degree relatives of patients with colorectal cancer in a healthcare region: a population-based, prospective study

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Background and study aims: A screening program in first-degree relatives (FDRs) of colorectal cancer (CRC) patients (index patients) was started in Trentino, Italy, to analyze factors that influence uptake of CRC screening among invited FDRs (first objective) and to describe colorectal findings among those undergoing colonoscopy (secondary objective).

Patients and methods: FDRs aged between 45 and 75 years were invited; exclusion criteria were: colonoscopy or barium enema in the preceding 5 years, a history of familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer, inflammatory bowel diseases, and severe comorbidities. FDRs who were eligible but were not invited for screening because consent was not obtained from the index patients were considered as the control group. FDRs were invited by the education campaign targeted at the population at risk (both study and control groups); in the study group, interventions targeting individuals at risk (letters, phone calls, face-to-face counseling) were implemented.

Results: Starting from 626 new index cases of diagnosed CRC, 725 FDRs were invited to counseling; 77.6% of these attended for colonoscopy in the study group vs. 8% in the control group ($P < 0.0001$). Predictors of colonoscopy uptake were FDR age above 60 years [odds ratio (OR) 2.50, 95%CI 1.72–3.62], complex family history (simple family history: one CRC at age above 60 years; complex family history: one CRC at age below 60 or two or more CRC; OR 1.54; 95%CI 1.04–2.33) and living in a rural area (OR 1.64, 95%CI 1.12–2.44). Of the 560 FDRs in the study group, 186 (33.8%) had adenomas, and 48 (8.8%) had advanced adenomas or cancer.

Conclusions: Interventions that target FDRs of patients with CRC, especially those younger than 60 years, with a complex family history of CRC and who live in a rural area, may improve uptake of CRC screening via colonoscopy.

Introduction

Colorectal cancer (CRC) is the second most common cause of death from cancer in Western countries. Individuals who have one or more first-degree relatives (FDRs) with diagnosed CRC present a two- to four-fold increased risk of this disease compared with the general population [1]. Colonoscopy is effective in CRC prevention [2] and is recommended as screening test, especially in people with two or more FDRs with CRC or one FDR with CRC diagnosed before the age of 60 [3,4]. In Western countries, the uptake of colonoscopy is low (28%–42%) among individuals with a family history of CRC [5–9]. In Italy, few studies have analyzed colonoscopy uptake in this group [10,11]. Many challenges are to be faced in the complex chain that makes up a CRC screening program in the primary care setting. Patient acceptance is a critical determinant since screening can only be effective when individuals take part. The rate of acceptance of colonoscopy can be improved by extensive education of both the public and general practitioners (GPs) in local communities.

The primary objective of this study is to evaluate whether a systematic and personalized program (letters, phone calls, and face-to-face counseling with a gastroenterologist) that targets individuals at increased risk will increase the uptake of colonoscopy compared to an extensive education campaign targeting the entire at-risk population. The secondary objective is to describe the prevalence of colorectal lesions in FDRs undergoing colonoscopy.

Method

Screening program setting

In 2005, the health authorities of the Trentino Region in Italy established a screening program for FDRs of patients with CRC. The Trentino Health Region – the Italian term is "Azienda Provinciale per i Servizi Sanitari", or APSS – is an alpine region located in Northern Italy with a catchment area of 500 000 inhabitants. It is a publicly funded healthcare system. Medical care is provided to residents of Trento (110 000 inhabitants) and Rovereto (40 000 inhabitants) and all small towns and villages (15 000 inhabitants or less) in the region. Twenty gastroenterologists from a total of nine public endoscopic practices took part in the screening program. The nine practices are located in community hospitals (Trento Santa Chiara, Trento San Camillo, Rovereto, Arco, Borgo Valsugana, Cavalese, Cles, Mezzolombardo, Tione) and accessible throughout the health region.

Screening design

From July to November 2005, study coordinators and local gastroenterologists met with GPs, surgeons, and oncologists in each healthcare district to explain the screening program. In addition, an extensive public education campaign was organized by public health authorities. The campaign consisted of leaflets and posters distributed in medical offices and hospitals, with local media involvement.

Beginning in December 2005, family histories were prospectively collected from patients with newly diagnosed CRC. For these index cases, endoscopic and pathology records were obtained. Health and demographic information on all FDRs (parents, siblings, and offspring) were obtained during a face-to-face interview between the physician and the index patients, and written consent to contact FDRs was obtained from each index patient. In cases where the index patient had died, family data were collected from a FDR. The data collected included name, sex, date of birth, address, health status of each relative, and previous evaluations of the lower gastrointestinal tract. Inclusion criteria for FDRs were: (1) either age between 45 and 75 years or up to 10 years younger than the youngest case of CRC in the family, and (2) residence in the Trentino Health Region. We chose to start screening individuals from 45 years of age, as high-risk adenomas and cancer have a low prevalence in younger relatives [2]. Exclusion criteria for FDRs were: (1) colonoscopy or barium enema in the 5 years preceding the study, or (2) history of familial polyposis or Lynch syndrome, inflammatory bowel diseases, and/or severe co-morbidity with reduced life expectancy. Data on the FDRs' health status and prior endoscopies collected from the index patients were compared with information contained in two population-based databases, the TESI database (Tesi Imaging, srl, Italy) in which gastroenterologists store data on endoscopic procedures, demographics, and clinical, endoscopic, and pathological diagnoses, and the Sistema Informatico Ospedaliero (SIO) database, in which clinical information including procedures, laboratory tests, and hospital discharge abstracts on APSS residents is stored. A coordinating center was instituted at Trento's Santa Chiara Hospital. A trained nurse gathered the data, sent letters, and took appointments for face-to face counseling and colonoscopies. A specific database for this screening program was designed and implemented; the nurse was responsible for the input of the data.

Invitation procedure

Eligible subjects were contacted by a standard letter, personalized to include the name of the index patient and signed by the study coordinator. The standard letter gave the FDRs information on the following: the lifetime risk of CRC in individuals at average risk and individuals with a family history of the disease; the concept of cancer prevention (finding and removal of benign polyps that might develop into cancer and early detection of cancer); the asymptomatic nature of polyps and early stages of cancer; and a description of colonoscopy. Patients were encouraged to consult their GPs and/or the coordinating center to obtain additional information. In the meantime, a similar letter was mailed to their GPs, who were asked to exclude patients according to the stated exclusion criteria. The letters were mailed within 2 months from collection of the family history. From two to three weeks later, FDRs were contacted by phone by the nurse at the coordinating center and invited to a face-to-face counseling appointment with a gastroenterologist. If the appointment was declined, they were re-contacted within 3 months; if they declined counseling a second time they were definitively excluded and a fecal occult blood test or barium enema was suggested. FDRs who were not resident in Trentino but were eligible on age grounds were contacted by a letter similar to the one mailed to local residents, suggesting that they undergo colonoscopy and asking them to send the report back to the coordinating center.

Flexible appointments were offered for counseling and colonoscopy. During a 20-minute consultation, the gastroenterologist discussed the risk of CRC, misconceptions and fears associated with colonoscopy (including sedation and bowel preparation), and problems concerning scheduling. When FDRs consented, colonoscopy was usually performed by the same gastroenterologist in the same endoscopic practice within 2 months from counseling. Participating gastroenterologists met every 6 months to update the screening program. Written informed consent was obtained from all participants. Every procedure, except preparation of the colon, was free of charge. Gastroenterologists received 60€ for each colonoscopy performed.

Control group

The control group consists of FDRs eligible for the screening program according to the inclusion and exclusion criteria but exposed only to the public education campaign because the index patients withheld permission to send a personalized invitation. Data on health status and endoscopic procedures in this group were collected retrospectively from the TESI and SIO databases.

Endoscopic procedures

Colonoscopies were performed using Pentax (EC 3840, EC 3801F, EC 3840F) or Olympus (CF-Q145I, CF-Q160I) instruments. Bowel preparation consisted of a suggested 72-hour low-residue diet and 4 L polyethylene glycol electrolyte solutions (SELG 1000, Promefarm, Milan, Italy or ISOCOLAN, Giuliani, Milan, Italy) taken the day before the examination. Informed consent was obtained from all patients. Opioids and benzodiazepines were used as needed for conscious sedation.

Procedure-related data recorded included quality of bowel preparation, type and dose of sedative administered, and cecal intubation rate. Inadequate preparation was generally defined by semisolid or solid stools that could not be suctioned or washed out. Cecal intubation was clearly stated in the reports when terminal ileum, appendiceal orifice, or ileocecal valve was specified.

Information on size, number, and histotype of colorectal polyps was obtained from endoscopic and pathology reports. Lesions were classified in three groups: hyperplastic polyps, nonadvanced adenomas, and advanced adenomas (> 10 mm and/or high-grade dysplasia and/or villous component greater than 25 %).

Data analysis

The screening program is ongoing. The cutoff point for this analysis was 31 December 2007. FDRs were considered to be compliant (to have taken up the screening offer) only after they had undergone colonoscopy; FDRs were not considered for the analysis if they had not yet been contacted by letter or phone call or if the colonoscopy had not been performed. The rate of uptake of counseling was defined as the percentage of FDRs counseled among those contacted and invited (number of FDRs who accepted counseling/number of FDRs contacted × 100). The rate of uptake of colonoscopy was defined as the percentage of FDRs who underwent colonoscopy among those contacted and invited to the counseling. We compared colonoscopy rates between FDRs invited and FDRs not invited to screening.

We decided to investigate the following potential predictors of screening uptake: age (< 60 years vs. ≥ 60 years) and sex of the index patient; age (< 60 years vs. 61 – 75 years), sex, and residence (urban – individuals living in Trento or Rovereto vs. rural – individuals living in other areas of the APSS region) of the FDR; family history (simple family history: one CRC at age > 60 years; complex family history: one CRC at age < 60 or two or more CRC), family relationship (children vs. siblings) of the FDRs, and sex of the GP. Differences in age, sex (both index patients and FDRs), and family history between FDRs with and without colorectal adenomas were assessed. Comparisons between the study groups were performed using Student's *t*-test, the χ^2 test, or Fisher's exact test. Univariate and multivariate analyses were calculated by using multiple logistic regression models; all reported P values are two-tailed with a significance level of less than 0.05; odds ratios (ORs) are presented with their corresponding 95 % confidence intervals (CIs). SPSS for Windows (version 14.0) was used for analyses.

Results

Of 626 patients newly diagnosed with CRC, 589 gave written consent for their FDRs to be contacted; 37 did not give permission. In total, 91 FDRs eligible for the screening program on the basis of age and residence could not be invited to screening because of lack of permission from these 37 index patients. Of the 91 FDRs who were not invited, 2 were excluded from the study because of a prior diagnosis of CRC, 1 because of co-morbidity, and 1 because of death; the remaining 87 were included in the final analysis. Data about excluded, eligible, and invited FDRs are shown in ▶ **Fig. 1**. Overall, 1065 FDRs were considered eligible, but 324 have been excluded from the study because they are yet to be contacted. Sixteen further FDRs were approached but the letters were returned undelivered and/or the telephone number was incorrect; these too are not counted as having been invited to counseling. Among the remaining 725 FDRs, who were successfully contacted and invited, 114 refused the invitation to counseling. The remaining 611 attended counseling (611/725; 83.9 %) and agreed to enter the screening program. Sixteen of these, however, were excluded at this point because it emerged during the counseling session that they had already undergone colonoscopy in the preceding 5 years. Now 595 FDRs remained, of whom 45 declined colonoscopy and 550 accepted and did indeed undergo it (550/595; 92.4 %). Overall, then, the uptake of colonoscopy was 75.9 % (550/725). If from the 725 FDRs invited to counseling we exclude the 16 not accepted because they had undergone colonoscopy in the preceding 5 years, the uptake rate was 77.6 % (550/709).

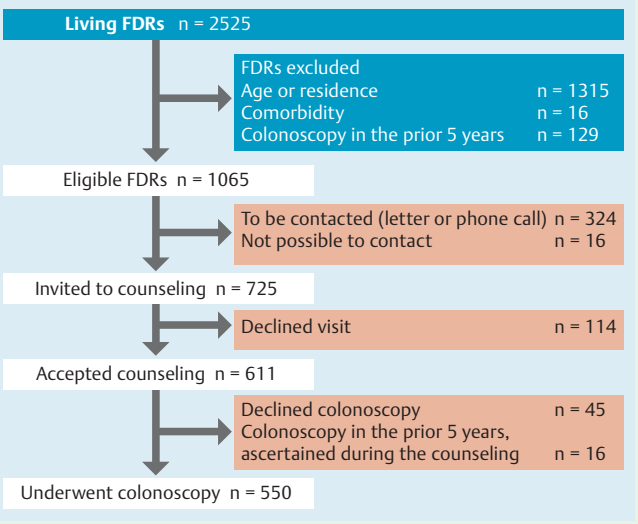

Fig. 1 Study population.

The uptake of colonoscopy was significantly higher among invited FDRs than in the control group (77.6 % vs. 8 %; $P < 0.0001$; ▶ **Table 1**); no differences were found in age, sex and residence between the two groups. Of 854 eligible FDRs, 145 (17 %) had undergone colonoscopy in the preceding 5 years (FDRs to be contacted and not possible to contact were excluded). On average, each of the 20 gastroenterologists performed 14.9 face-to face counselings per year (595/20 in two years) and 13.7 colonoscopies per year (550/20 in two years). Four percent of nonresident

Characteristics	Invited* (n = 709)	Not invited (n = 87)	*P*
Age (mean SD)	57.4 (10.1)	59.0 (12.0)	0.55
Sex (%)			
Male	51.5	50.6	0.87
Female	48.5	49.4	
Residence (%)			
urban	30.5	35.6	0.33
rural	64.4	69.5	
Uptake of colonoscopy (%)	77.6	8.0	0.001

* The 16 FDRs with colonoscopy in the preceding 5 years, ascertained during the counseling, were excluded.

Table 1 Comparison of demographic characteristics and uptake of colonoscopy between FDRs who were invited and those who were not invited.

FDRs (4/110) sent in the results of their colonoscopy after receiving the request from the coordinating center.

Univariate predictors of increased screening rates were age of the index patient above 60 years, complex family history, age of FDRs <60 years, and living in a rural area (**Table 2**). The screening rates of offspring were higher than those of siblings, but the difference did not achieve statistical significance (81.8% vs. 75.7%; $P = 0.07$). Multivariate predictors of screening uptake were age of FDR <60 years, complex family history, and living in a rural area (**Table 3**).

The cecum was reached in 539 of 550 examinations (98%); sedation/analgesia (benzodiazepine IV, opiate IV, or a combination of the two) was used in 78.9% of subjects; propofol was administered in 1% of the procedures; bowel cleansing was judged inadequate in 9 of 550 examinations (1.6%). A total of 4 complications were observed. These were 2 cases of immediate and 1 case of late post-polypectomy bleeding (0.54%) that required endoscopic therapy, plus 1 case of colonic perforation that occurred after polypectomy (0.18%) and required surgical repair. No deaths were reported.

Two hundred fifty-three patients (46%) of the FDRs who underwent colonoscopy had polyps. Sixty-seven (12.2%) had hyperplastic polyps only; 186 (33.8%) had adenomas or invasive cancer. Forty-one (7.5%) had advanced adenomas and 7 (1.3%) had cancer: 6 a T1N0M0 stage tumor and one a T2N0M0 stage tumor. On average, FDRs with adenomas were older than FDRs without adenomas (59.3 years vs. 54.7 years; $P < 0.001$; **Table 4**). Adenomas were more frequent in male FDRs (41.4% vs. 25.2%; $P < 0.001$; **Table 4**). Among FDRs with adenomas, age was significantly higher in patients with advanced adenomas (63.2 years vs. 57.4 years; $P < 0.001$; **Table 5**), and advanced adenomas were more frequent in males (39.7% vs. 21.5%; $P = 0.001$; **Table 5**). There was a higher prevalence of advanced adenomas in FDRs when the index case was male (39.3% vs. 25.3%; $P = 0.033$; **Table 5**); no differences were found in FDRs with a higher degree of familial aggregation.

Table 2 Characteristics of index cases and relatives associated with adherence rate among invited FDRs.

Characteristics	Results (%)	*P*
Age of index patient		
<60 years	86.9	<0.001
≥60 years	74.2	
Sex of index patient		
Male	78.1	0.63
Female	76.6	
Family relationship		
Sibling	75.7	0.07
Child	81.8	
Family history		
Simple	73.8	0.004
Complex	82.9	
Age of FDR		
<60 years	84.3	<0.001
≥60 years	67.4	
Sex of FDR		
Male	80.0	0.11
Female	75.0	
Residence FDR		
Urban	71.8	0.015
Rural	80.1	
Sex GPs		
Male	76.3	0.119
Female	83.1	

Table 3 Independent variables associated with uptake of colonoscopy

Characteristics	OR (95%CI)	*P*
Age of FDR <60 vs. ≥60 years	2.50 (1.72–3.62)	<0.001
Family history complex vs. simple	1.54 (1.04–2.33)	0.03
Residence rural vs. urban	1.64 (1.12–2.44)	0.01

Discussion

In CRC screening programs, the uptake of testing by people at average risk is low [12,13]. Risk factors such as family history do not increase attendance rate; uptake of colonoscopy among FDRs is 28%–42% in both retrospective and prospective studies from Western countries [5–9]; in patients with a family history of colorectal adenomas it is even lower (18%) [14]. In Italy, a 5-year screening program in FDRs of patients with CRC [11] reported higher colonoscopy rates (72%) than other studies [5–9]. However, in that study family history was not collected systematically from index patients and the total number of FDRs is unknown. The authors were unable to contact and invite all FDRs, and data on FDRs who refused face-to face counseling are lacking. The study considered only subjects who spontaneously contacted the screening center, and this may have overestimated the rate of screening uptake. In another study in Italy, colonoscopy uptake among FDRs was 29.9% [10].

In our screening program we have made a dedicated and systematic effort to identify and invite FDRs of patients with CRC to receive face-to-face counseling with a gastroenterologist and undergo colonoscopy, both free of charge. The attendance rate (77.6%) was higher than the rate found in the control group (8%) and in the historical controls [5–9].

The determinants of screening behavior are complex [15–17]. Patients with CRC generally know little about the increased risk of CRC among their FDRs [9], and the low uptake of colonoscopy in retrospective studies [6,7,9] demonstrates that only a minority of patients are aware that they are at increased risk of CRC because of family history. An extensive information campaign promoting the project at the community level and involving public authorities, GPs, and local media might influence the rate of screening uptake, and extensive public education might raise the perceived risk of CRC and its risk factors in the general population. However, a campaign with standard information targeting the entire population at risk did not result in a high uptake of colonoscopy in our study, as observed in the control group.

Although we cannot tell which intervention factors targeted at individuals contributed to the final results, we would speculate that face-to-face advice given by a gastroenterologist might have played an important role. Low uptake was observed in studies in which only a letter was mailed [8]; after face-to face counseling, 92.4% of FDRs underwent colonoscopy in our study and 72% of FDRs who spontaneously contacted the screening center in another Italian study [11]. On the other hand, a low uptake of colonoscopy was achieved in Spain [5] despite face-to-face counseling with a gastroenterologist. We are unable to explain these differences, but sufficient time devoted to the patients for a tailored

Characteristics	Adenomas (n = 186)	No adenomas (n = 364)	*P*
Age (mean SD) of the index patients	69.1 (12.0)	67.3 (13.2)	0.13
Sex (%) of the index patients			
Male	32.8	67.2	0.29
Female	35.4	64.6	
Age (mean SD) of FDRs	59.3 (9.2)	54.7 (9.2)	<0.001
Sex (%) of FDRs			
Male	41.4	58.6	<0.001
Female	25.2	74.8	
Family history			
Simple	35.8	64.2	0.15
Complex	31.3	68.7	

Table 4 Variables associated with adenomas: adenomas vs. no-adenomas.

Characteristics	Advanced adenomas (n = 62)	Non-advanced adenomas (n = 124)	*P*
Age (mean SD) of the index patients	67.8 (12.1)	69.7 (12.5)	0.29
Sex (%) of the index patients			
Male	39.3	59.2	
Female	25.3	74.7	0.03
Age (mean SD) of FDRs	63.2 (8.8)	57.4 (8.8)	<0.001
Sex (%) of FDRs			
Male	39.3	60.3	<0.001
Female	21.5	78.5	
Family history			
Simple	32.7	67.3	0.48
Complex	34.2	68.7	

Table 5 Variables associated with adenomas: advanced adenomas vs. non-advanced adenomas.

discussion of all their concerns about screening and colonoscopy may have played a part.

Other factors that improved uptake might be related to the healthcare organization: FDRs were contacted shortly after the CRC was diagnosed in their relatives; face-to face counseling sessions and colonoscopy procedures for which arrangements were flexible were fully covered by an entirely public-funded system; gastroenterologists were paid for their work; and endoscopic practices with sufficient colonoscopy personnel to face the colonoscopy demand were widespread throughout the alpine area.

In our population, uptake of colonoscopy was higher among FDRs with a complex family history (OR 1.54; 95%CI 1.04–2.33; $P = 0.03$); knowledge about the disease had a greater impact on awareness of risk in families in which the index patient was young and/or multiple members were affected. An age under 60 of FDRs who attended for colonoscopy (OR 2.50, 95%CI 1.72–3.62; $P < 0.001$) was observed in our study and in others [5,8], and could reflect competing co-morbidities and shorter life expectancy in older people. Increased uptake by FDRs living in rural areas (OR 1.64, 95%CI 1.12–2.44; $P = 0.01$) may be due to easy, early access to endoscopic practices close to their home. We found no differences in screening rates in relation to the sex of the GP, although previous studies have indicated that female physicians are more likely to deliver preventive services [18]; this absence of difference may be due to the fact that colonoscopy is a non-sex-specific cancer screening test.

In our population, the prevalence of advanced adenomas is similar to those found in FDRs of patients with CRC [5,19,20] or large adenomas [21] from other countries. The high frequency of lesions detected in our population and the projected annual transition rates [22] from advanced adenoma to colorectal cancer (2.6%–5.6%) underline the role colonoscopy has to play in detecting precancerous polyps and thus in reducing CRC risk; colonoscopy is effective in CRC prevention in this high-risk population [2]. A significantly higher percentage of advanced adenomas was found in older FDRs and in males; furthermore, a link between male sex of the index patients and family risk of advanced adenomas has been found – in fact, recent data [21] suggest that the familial risk in FDRs might also depend on the characteristics of the affected family member. Identification of risk factors that allow risk stratification in this high-risk group could help to refine CRC screening recommendations [23].

There are some limitations to our study. The number of FDRs in the control group is small. There are also uncertainties about the validity of screening data in this group: since we cannot contact these patients directly, data about colonoscopy rates cannot be accurate because they were collected retrospectively. The colonoscopy rate is very low among the control group compared with the study group, and lower than that observed in other studies [5–9]. The TESI and SIO databases store clinical and endoscopic data on persons living in the APSS: some FDRs might undergo colonoscopy in other healthcare regions, or may undergo colonoscopy in the near future. This screening program was recently implemented in the APSS area. Extensive public education might raise the perceived risk of CRC and its risk factors in this population, and the program could become more popular among the population in the future. In the APSS, the uptake of voluntary, insurance-paid colonoscopy among average-risk subjects aged between 45 and 75 is 0.7% (data from SIO and TESI databases). The uptake of fecal occult blood tests among invited and insurance-paid average-risk subjects aged between 50 and 69 is 58% in this APSS [24]. In addition, the low uptake in the control arm may also be due to the following confounding factors: the control group consisted of FDRs of patients who refused to take part in the screening program. This refusal may reflect an attitude towards health care which may also be present in the FDRs

of these patients, thus lowering the likelihood of them participating in screening programs. Another limitation of our study is that of the 1065 FDRs that were considered eligible, 324 were excluded because they have not yet been contacted. We cannot be sure that this is a random sample that is likely to have the same rate of uptake of the screening program.

Our study focused on a one-time invitation for colonoscopy; we have no data about programmatic uptake of repeat screening test and predictors of it, especially in those with a negative colonoscopy result; at present, we suggest colonoscopy every 5 years for those with a complex family history and every 10 years for those with a simple family history. Furthermore, data about the performance of the program, such as impact on the incidence of CRC and CRC mortality rates, are needed. Its generalizability may be limited by the facts that we have an entirely publicly funded healthcare system, this is a pay-for-performance initiative targeted at gastroenterologists, and there are a large number of colonoscopy personnel working in the APSS (4.08 gastroenterologists per 100 000 population) compared to Canada or the United Kingdom (1.83 and 1.41 per 100 000 respectively) [25]. Our study focused on patients at high risk of CRC, so results are not comparable to figures for those at average risk. In the present study we describe colonoscopic findings in our population but we have not compared them with a control group; when we compared these findings with the prevalence of colorectal adenoma in average-risk individuals undergoing colonoscopy as primary screening tool, a higher prevalence of both colorectal adenomas and advanced colorectal adenomas was found in FDRs [26].

In summary, this study reports one of the highest rates of uptake of colonoscopy in CRC screening programs, but it is limited to FDRs of index patients with CRC and does not involve the entire population. The novel implication arising from this study is that a public health model that employs a systematic and organized screening program targeting the individuals at risk in a personalized way, and involves both GPs and endoscopists, might be a successful initial contact strategy to increase the rate of uptake of screening colonoscopy among FDRs of patients with CRC, especially if they are younger than 60 years, have a complex family history of CRC, and live in a rural area. Promoting the uptake of CRC screening in this high-risk population can be seen as a sensible first step to improving the success of CRC screening programs.

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