

Exploring the Perceived Risk of Complications in Endoscopic Screening Procedures

João Carlos Silva^{a, b} Mário Dinis-Ribeiro^{b, c} Fernando Tavares^d
Diogo Libânio^{b, c}

^aGastroenterology Department, Unidade Local de Saúde Gaia e Espinho (ULSGE), Vila Nova de Gaia, Portugal;
^bMEDCIDS, Faculty of Medicine, University of Porto, Porto, Portugal; ^cGastroenterology Department, RISE@CI-IPOP (Health Research Network), Portuguese Oncology Institute of Porto (IPO Porto) & Porto Comprehensive Cancer Centre (Porto.CCC), Porto, Portugal; ^dStudies and Planning Department, Administração Regional de Saúde do Norte (ARSN), Porto, Portugal

Keywords

Gastrointestinal endoscopy · Cancer screening · Early cancer detection · Endoscopy-related complications · Adverse events · Preventive medicine · Risk perception

Abstract

Background and Aims: Endoscopy holds a pivotal role in colorectal (CRC) and gastric cancer screening, and adherence rates might be impacted by the patient's risk perception, encompassing concerns about complications during endoscopic screening procedures. This study aimed to evaluate how individuals perceive the risk of complications associated with undergoing a screening colonoscopy and upper gastrointestinal endoscopy (UGIE). **Methods:** This is a cross-sectional study enrolling individuals eligible for CRC screening in northern Portugal, where a populational fecal occult blood test program is implemented. The validated PERCEPT-PREVENT tool was applied through telephonic interviews in 2 groups: (a) never-screened and (b) already submitted to endoscopic

screening. **Results:** Among the 217 included healthy participants, 61% ($n = 133$) and 83% ($n = 181$) were unaware of any possible complications from colonoscopy and UGIE, respectively. Never-screened individuals less frequently reported a high complication risk perception (colonoscopy: 19% vs. 45%, $p < 0.001$; UGIE: 14% vs. 41%, $p < 0.001$). A lower risk perception for UGIE complications was associated with a higher willingness to undergo UGIE combined with a screening colonoscopy (OR: 2.30, 95% confidence interval: 1.42–3.70). Participants who underwent combined screening reported less frequently a high complication risk perception (colonoscopy: 27% vs. 61%, $p < 0.001$; UGIE: 28% vs. 54%, $p = 0.006$) and scored higher for complication awareness (colonoscopy: 14 ± 5 vs. 11 ± 4 , $p < 0.001$; UGIE: 11 ± 4 vs. 9 ± 3 , $p < 0.001$) compared to those who had only undergone colonoscopy. **Discussion:** Enhancing risk perception and knowledge of complications associated with endoscopic screening procedures offers an opportunity to increase adherence rates.

© 2024 The Author(s).
Published by S. Karger AG, Basel

Perceção do risco de complicações em procedimentos endoscópicos de rastreio

Palavras Chave

Endoscopia digestiva · Rastreio oncológico · Detecção precoce · Complicações · Eventos adversos · Medicina preventiva · Perceção do risco

Resumo

Objetivos: A endoscopia digestiva desempenha um papel central no rastreio de neoplasias do trato digestivo. A adesão ao rastreio pode ser influenciada pela perceção do risco de complicações. O objetivo deste estudo foi avaliar a perceção do risco de complicações associadas à colonoscopia e à endoscopia digestiva alta (EDA) em contexto de rastreio.

Métodos: Estudo transversal com inclusão de indivíduos elegíveis para o programa de rastreio de cancro colorretal, implementado na região norte de Portugal. O questionário PERCEPT-PREVENT, previamente validado, foi aplicado através de entrevistas telefónicas em 2 grupos: a) sem rastreio prévio, e b) rastreio endoscópico prévio. **Resultados:** Foram incluídos 217 participantes, dos quais 61% ($n = 133$) e 83% ($n = 181$) desconheciam qualquer complicação da colonoscopia e da EDA, respetivamente. Indivíduos sem rastreio prévio reportaram com menor frequência uma perceção alta do risco de complicações (colonoscopia: 19% vs. 45%, $p < 0,001$; EDA 14% vs. 41%, $p < 0,001$). Uma menor perceção do risco de complicações da EDA associou-se a uma maior intenção de aceitar a EDA combinada com uma colonoscopia de rastreio (OR: 2,30, IC95%: 1,42–3,70). Participantes previamente submetidos a rastreio combinado reportaram, com menor frequência, uma perceção alta do risco de complicações (colonoscopia: 27% vs. 61%, $p < 0,001$; EDA: 28% vs. 54%, $p = 0,006$) e obtiveram pontuações mais altas no reconhecimento das possíveis complicações (colonoscopia: 14 ± 5 vs. 11 ± 4 , $p < 0,001$; EDA: 11 ± 4 vs. 9 ± 3 , $p < 0,001$) quando comparados com indivíduos submetidos apenas a colonoscopia.

Discussão: Otimizar o conhecimento sobre as complicações dos procedimentos endoscópicos de rastreio oferece uma oportunidade para aumentar as taxas de adesão.

© 2024 The Author(s).

Published by S. Karger AG, Basel

Introduction

Gastrointestinal (GI) endoscopy is a minimally invasive procedure that carries a risk of complications, which may be heightened by additional diagnostic or therapeutic interventions. Informed consent must be obtained before each procedure to ensure patient autonomy and is signed by the patient or, in cases of incapacity, by their legal representative [1]. In this context, medicolegal issues are increasingly relevant even for commonly performed endoscopic procedures such as a screening colonoscopy [2].

GI endoscopy plays a fundamental role in digestive cancer screening [3]. In Europe, most countries have implemented populational colorectal cancer (CRC) screening programs based on fecal occult blood testing (FOBT), while colonoscopy screening is offered as the primary method in Poland [4, 5]. Upper GI endoscopy (UGIE) is the primary screening method for gastric cancer (GC) in high-incidence countries (age-standardized incidence rate ≥ 20 per 100,000) [6]. For intermediate-risk regions, with an age-standardized incidence rate between 10 and 20 per 100,000, UGIE may have a role for primary screening if cost-effectiveness is proven [3]. Data from Portuguese cost-utility analyses concluded that endoscopic screening for GC was cost-effective when combined with a screening colonoscopy [7, 8]. Therefore, endoscopic screening can be considered based on local settings, including the costs of endoscopic procedures and the availability of endoscopic resources [3, 8].

Apart from concerns about patient autonomy and medicolegal issues, patients' risk perception, particularly regarding complications, may impact digestive cancer screening uptake. Adherence to screening encompasses the perceived risk of developing cancer but also the perceived barriers, particularly the risk of complications during endoscopic screening procedures. A previous study comparing never-screened individuals with individuals previously screened for CRC evaluated the complication risk perception and found that never-screened individuals were more likely to overestimate the risk of complications from a colonoscopy than patients already submitted to screening (38% vs. 19%; $p = 0.04$) [9].

This study aimed to assess the perceived risk of endoscopy-related complications within the context of CRC and GC screening. Additionally, the study aimed to measure the impact of perceived complication risk on screening uptake.

Materials and Methods

Study Design and Procedures

This was a cross-sectional study including asymptomatic individuals aged 50–75 years eligible for CRC screening in the northern region of Portugal where a populational fecal immunochemical test (FIT) screening program was implemented in 2018 under the coordination of *Administração Regional de Saúde do Norte* (ARSN). The study protocol was approved by the Ethical Committees of the 3 institutions involved in the study, namely, ARSN, *Unidade Local de Saúde Gaia Espinho*, and *Instituto Português de Oncologia do Porto*. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies were used [10].

In the populational FIT screening program, eligible citizens are directly invited by regular mail, initially through an awareness letter, and subsequently, a kit for stool sample testing is sent, along with instructions on how to perform the test and deliver it to the Primary Care Center [11]. Those who test positive are invited to undergo a pre-colonoscopy assessment, performed by the primary care physician, and then referred for a sedated colonoscopy at the nearest Portuguese National Health Service (NHS) hospital. Both screening tests, namely, FIT and colonoscopy, are offered free of charge. All FITs (OC-Auto Sampling 3, Eiken Chemical Co., Ltd.) undergo analysis at a centralized laboratory, while a centralized information platform (Electronic Screening Management Platform) oversees all pertinent outcomes of the organized screening program.

GC screening is neither implemented nor recommended, although primary care physicians are allowed to order UGIE (and colonoscopies) at their discretion. These endoscopic procedures are performed in clinics, and the patients incur no costs, being those supported by the NHS. The NHS also covers sedation costs for colonoscopy but not for stand-alone UGIE. However, in the northern region of Portugal, if a patient is prescribed a colonoscopy with sedation plus a non-sedated UGIE, most private clinics do not charge additional costs for UGIE sedation. In the case of stand-alone UGIE, the NHS covers the cost of the UGIE, but the patient covers sedation costs (around EUR 80–120).

The study design relied on the comparison of two predefined groups: (a) never-screened individuals and (b) patients already submitted to endoscopic screening

(primary colonoscopy, colonoscopy after a positive FOBT, or primary colonoscopy combined with UGIE), with or without sedation. Individuals who tested negative for FOBT as well as FOBT-positive individuals who refused colonoscopy screening were excluded. Further exclusion criteria encompassed patients with either upper or lower GI symptoms (e.g., diarrhea, constipation, abdominal pain, weight loss, hematochezia, dysphagia, heartburn, nausea, vomiting, hematemesis); anemia; previous CRC, GC, or colorectal polyps; precancerous gastric conditions; known hereditary cancer risk (including first-degree relatives with CRC and/or GC); previous colectomy; previous gastrectomy; inflammatory bowel disease; dementia; inability and/or refusal to answer the questionnaire.

Contacts of individuals eligible for CRC screening were extracted from the ARSN database based on their screening status from November 2021 to April 2022. Participants were randomly selected through a stratified random sample, according to sex and age groups (50–59 years old and 60–74 years old). Screening status assessment and data extraction were completed in August 2022. Individuals who underwent CRC screening through primary colonoscopy (outside the populational program) were recruited from 3 different private endoscopy units, from July 2022 to April 2023, after assessment of inclusion and exclusion criteria.

Percept-Prevent Tool

A previously validated risk perception questionnaire (PERCEPT-PREVENT tool) that targets both CRC and GC as well as endoscopy-related complications was used [12]. In the section of the survey focusing on barriers to screening, negative health consequences of colonoscopy and UGIE were assessed, including the perception of possible corporal harm (defined as “complication risk perception”), physical discomfort, fear, and embarrassment. Knowledge of possible endoscopy-related complications was evaluated in two steps. First, participants were asked to enumerate known complications for colonoscopy and UGIE (“complication knowledge score”). Subsequently, participants were presented with a detailed list and instructed to identify which were, in their perspective, possible complications of a sedated colonoscopy and UGIE (“awareness of possible complications”). The complete version of the PERCEPT-PREVENT tool has been previously detailed [12] and is also presented as an online supplementary appendix (for all online suppl. material, see <https://doi.org/10.1159/000543180>) (online suppl. appendix 1 and 2).

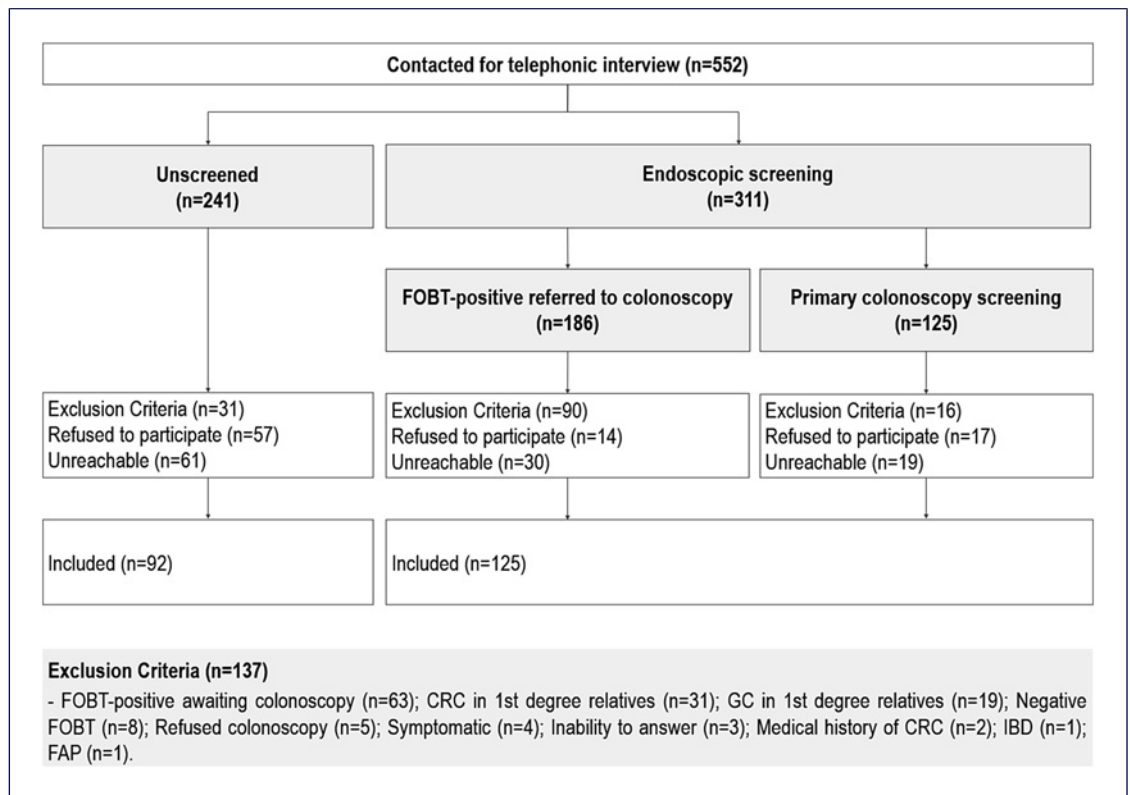


Fig. 1. Study population according to the screening status. CRC, colorectal cancer; FAP, familial adenomatous polyposis; FOBT, fecal occult blood test; GC, gastric cancer; IBD, inflammatory bowel disease.

The PERCEPT-PREVENT tool questionnaire was administered remotely via telephonic interview, within a period of up to 6 months after the screening status assessment, from September 2022 to September 2023. Interviews were conducted by 2 gastroenterology nurses after three formal training sessions, and informed verbal consent was obtained from all participants. The PERCEPT-PREVENT answers were recorded in an electronic database, and each patient received a code number to secure anonymization. Sociodemographic data including age, gender, educational level, and monthly income were registered.

Sample Size Calculation and Statistical Analysis

The primary endpoint of the study, used for sample size calculation, was the perceived risk of colonoscopy complications. Considering previously reported complication rate perception of 38% for never-screened and 19% for screened individuals [9], we calculated that 85 participants in each group were needed to demonstrate a 19% difference between groups, with a 95% confidence interval (CI), an error of 0.05, and a power of 80%.

Statistical Package for Social Sciences (SPSS) program version 28 (IBM Corporation, Armonk, NY) was used. Categorical variables are summarized as frequencies and percentages. As appropriate, the χ^2 test or Fisher's exact test was used to compare categorical variables. Normal distribution was examined using histogram visual inspection. Continuous variables were expressed in means and standard deviation (variables with normal distribution) or median and interquartile range (variables with skewed distributions). The independent samples *t* test or independent samples Mann-Whitney U test were used to compare two groups. Spearman's correlation coefficient was used to evaluate the correlation between complication risk perception scores. To assess the impact of risk perception on screening uptake (intention to undergo CRC screening, preferred method of CRC screening, and willingness to undergo UGIE combined with a screening colonoscopy), the domains of the PERCEPT-PREVENT tool targeting perception of colonoscopy and UGIE complications were evaluated. All reported *p* values are two-tailed, with a *p* value <0.050 indicating statistical significance.

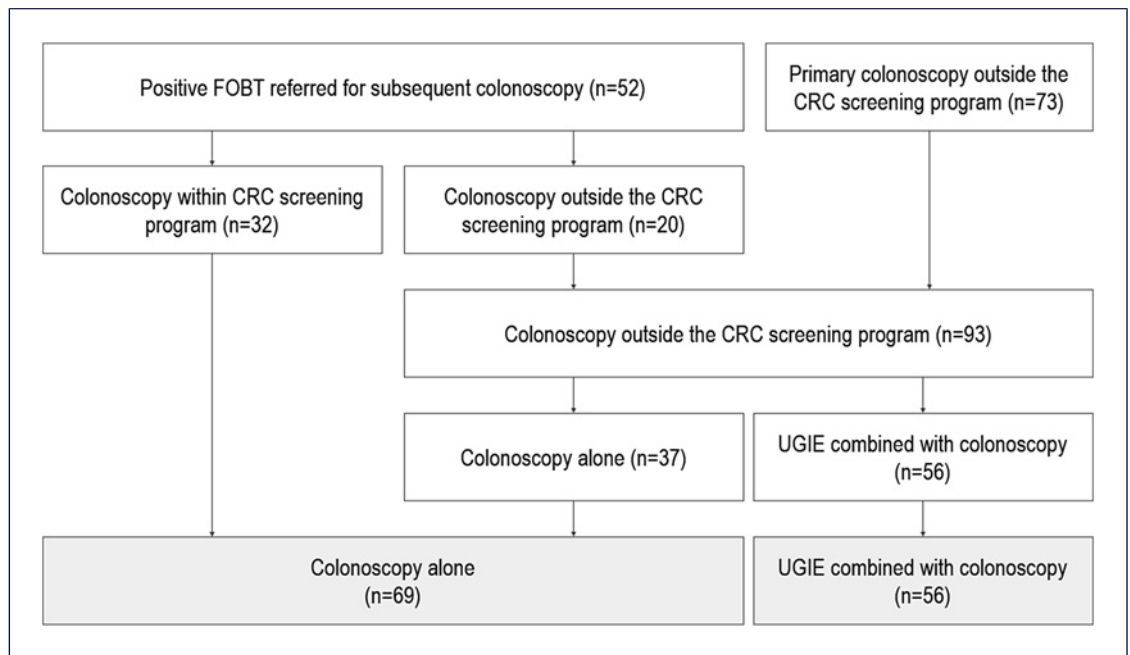


Fig. 2. CRC and GC endoscopic screening. CRC, colorectal cancer; FOBT, fecal occult blood test; UGIE, upper gastrointestinal endoscopy.

Results

Study Population and Recruitment Procedures

A total of 552 individuals were contacted for telephonic interviews. Of these, 137 met exclusion criteria, 110 were unreachable, and 88 refused to participate in the telephone interviews, regardless of their screening status (Fig. 1). A total of 217 healthy participants were included, comprising 92 never-screened individuals and 125 who had already undergone endoscopic screening. Among screened participants, 32 (26%) underwent colonoscopy within the organized CRC screening program and the remaining 93 (74%) were screened in private endoscopy units. Previous screening through FIT and/or colonoscopy was reported in 13.6% ($n = 17$). Accordingly, none of the individuals in the never-screened group reported previous screening. Concerning screened respondents, most were submitted to UGIE combined with a screening colonoscopy (60%; $n = 56$) (Fig. 2).

The mean age was 55 ± 7 years, and 56% ($n = 122$) were female. Regarding sociodemographic features, 57% ($n = 121$) were married, 53% ($n = 112$) had a basic educational level (sub-high school educational attainment), and 29% ($n = 62$) had health insurance. Data on sociodemographic characteristics and attitudes toward digestive cancer screening are shown in Table 1.

Risk Perception of Endoscopy-Related Complications

Overall, knowledge of complications was low: 61% ($n = 133$) and 83% ($n = 181$) of the individuals did not know (did not name) any possible complication for colonoscopy and UGIE, respectively. In detail, among participants who reported knowledge of at least one possible complication (colonoscopy: $n = 84$; UGIE: $n = 36$), perforation and bleeding were the most commonly identified complications (colonoscopy: 96% and 41%, respectively; UGIE: 97% and 36%, respectively).

Never-screened individuals less frequently reported a high complication risk perception, both for colonoscopy (19% vs. 45%; $p < 0.001$) and UGIE (14% vs. 41%; $p < 0.001$). There was a strong positive correlation between the perceived complication risk for colonoscopy and UGIE ($r = 0.68$; $p < 0.001$).

Irrespective of previously reported knowledge on colonoscopy and UGIE complications, participants were subsequently presented with a detailed list of complications and instructed to identify which, in their perspective, were possible complications of a screening colonoscopy and UGIE (Table 2). A higher rate of affirmative answers was obtained for perforation (colonoscopy: 96%, $n = 185$; UGIE: 94%, $n = 175$), bleeding (colonoscopy: 84%, $n = 147$; UGIE: 79%, $n = 132$), and infection (colonoscopy: 63%, $n = 100$; UGIE: 56%, $n = 84$). There were no significant differences across groups,

Table 1. Sociodemographic characteristics and attitudes towards digestive cancer screening ($n = 217$)

Female, n (%)	122 (56)
Age, mean (SD)	55 (7)
Married, n (%)	121 (57)
Basic educational level, n (%)	112 (53)
Active worker, n (%)	141 (67)
Intermediate monthly income (EUR 500–1,000), n (%)	22 (43)
Regular follow-up with primary care physician, n (%)	212 (98)
Health insurance, n (%)	62 (29)
Informed on CRC screening tests from any means of communication, n (%)	141 (65)
CRC in second-degree relatives or acquaintances, n (%)	63 (29)
Second-degree relatives with CRC, n (%)	32 (15)
Intention to undergo CRC screening, n (%)	210 (97)
Preferred primary method of CRC screening, n (%)	
FOBT	49 (23)
Colonoscopy	161 (77)
Informed on GC screening tests from any means of communication, n (%)	100 (47)
GC in second-degree relatives or acquaintances, n (%)	52 (24)
Second-degree relatives with GC, n (%)	26 (12)
Willing to undergo UGIE for GC screening combined with a screening colonoscopy, n (%)	206 (95)

CRC, colorectal cancer; GC, gastric cancer; SD, standard deviation.

except for the higher perceived risk of allergy to drugs administered during the procedure among endoscopically screened respondents (colonoscopy: 71% vs. 45%, $p = 0.005$; UGIE: 62% vs. 40%, $p = 0.016$) and higher perceived risk of infection in never-screened participants (colonoscopy: 79% vs. 56%, $p = 0.005$; UGIE: 67% vs. 50%, $p = 0.045$). Death was acknowledged as a possible adverse outcome of colonoscopy by 65% ($n = 98$) and of UGIE by 60% ($n = 96$).

For both colonoscopy (90%; $n = 194$) and UGIE (97%; $n = 211$), most participants did not know any factor that increases the risk of endoscopy-related complications (Table 3). Among the 22 participants (10%) who reported knowledge of risk factors for colonoscopy complications, 86% ($n = 19$) identified inadequate bowel preparation, while 18% ($n = 4$) mentioned anticoagulants, antiplatelets, or bleeding disorders. Only 6 participants (3%) reported knowledge of risk factors for UGIE complications, and 3 of these specified inadequate fasting.

Impact of the Perceived Risk of Endoscopy-Related Complications on Screening Uptake

Concerning CRC screening, complication risk perception and complication knowledge did not impact either intention to adhere or the preference for any screening method (online

suppl. Table 1). However, a lower risk perception for UGIE complications was significantly associated with a higher willingness to undergo an UGIE combined with a screening colonoscopy (OR: 2.25, 95% CI: 1.29–3.92).

Among participants already submitted to endoscopic screening, those submitted to combined screening reported less frequently a high complication risk perception for both colonoscopy (27% vs. 61%; $p < 0.001$) and UGIE (28% vs. 54%; $p = 0.006$) when compared with individuals submitted to colonoscopy alone (online suppl. Table 2). Additionally, in this subset of individuals, a significantly higher proportion of participants reported knowledge of at least two possible colonoscopy complications (45% vs. 26%; $p = 0.030$). Awareness of complications was also higher in the combined screening group (colonoscopy: 14 ± 5 vs. 11 ± 4 , $p < 0.001$; UGIE: 11 ± 4 vs. 9 ± 3 , $p < 0.001$). In the latter, bleeding (colonoscopy: 91% vs. 70%, $p = 0.005$; UGIE: 88% vs. 66%, $p = 0.008$), infection (colonoscopy: 78% vs. 35%, $p < 0.001$; UGIE: 76% vs. 21%, $p < 0.001$), and cardiorespiratory complications (colonoscopy: 73% vs. 43%, $p < 0.017$; UGIE: 64% vs. 22%, $p < 0.001$) were correctly identified in a significantly higher rate. Likewise, death was more frequently considered as a potential adverse outcome of colonoscopy (84% vs. 50%; $p < 0.001$) and of UGIE (75% vs. 47%; $p = 0.003$).

Table 2. Awareness of possible complications during endoscopic screening procedures

	Total (N = 217)	Never-screened (N = 92)	Endoscopically screened (N = 125)	p value
<i>Colonoscopy</i>				
Awareness of possible complications during a colonoscopy (0–26) ^a , mean (SD)	13 (4)	14 (4)	13 (5)	0.089
Abdominal pain, n (%)	52 (33)	12 (28)	40 (35)	0.375
Fever, n (%)	9 (6)	1 (3)	8 (8)	0.335
Nausea and/or vomiting, n (%)	46 (32)	13 (38)	33 (30)	0.368
Headache and/or dizziness, n (%)	25 (18)	5 (19)	20 (18)	0.920
Perforation, n (%)	185 (96)	69 (96)	116 (96)	0.991
Bleeding, n (%)	147 (84)	53 (90)	94 (80)	0.109
Infection, n (%)	100 (63)	38 (79)	62 (56)	0.005
Injury in other organs (e.g., spleen rupture), n (%)	2 (4)	0 (0)	5 (5)	1.000
Acute appendicitis, n (%)	1 (3)	1 (14)	0 (0)	0.200
Acute diverticulitis, n (%)	1 (3)	1 (14)	0 (0)	0.219
Cardiorespiratory complications ^b , n (%)	60 (58)	18 (49)	42 (64)	0.139
Allergy to drugs administered during the procedure, n (%)	75 (63)	18 (45)	57 (71)	0.005
Death, n (%)	98 (65)	30 (63)	68 (67)	0.617
<i>UGIE</i>				
Awareness of possible complications during a UGIE (0–20) ^a , mean (SD)	10 (4)	10 (4)	10 (4)	0.480
Abdominal pain, n (%)	38 (25)	6 (15)	32 (29)	0.079
Fever, n (%)	7 (5)	2 (6)	5 (5)	0.730
Nausea and/or vomiting, n (%)	57 (39)	13 (35)	44 (40)	0.573
Headache and/or dizziness, n (%)	31 (22)	6 (18)	25 (24)	0.453
Perforation, n (%)	175 (94)	68 (93)	107 (95)	0.664
Bleeding, n (%)	132 (79)	48 (83)	84 (77)	0.389
Infection, n (%)	84 (56)	33 (67)	51 (50)	0.045
Cardiorespiratory complications ^b , n (%)	50 (47)	16 (42)	34 (50)	0.435
Allergy to drugs administered during the procedure, n (%)	65 (54)	17 (40)	48 (62)	0.016
Death, n (%)	96 (60)	29 (58)	67 (61)	0.728

SD, standard deviation; UGIE, upper gastrointestinal endoscopy. ^aCalculated by summing the score for each possible complication ("yes": 2 points; "do not know": 1 point; "no": 0 points). ^bIncludes acute myocardial infarction, thrombosis, stroke, and arrhythmia.

Discussion

Individuals who had never undergone screening had a lower perception of the risk of complications from a screening colonoscopy and UGIE. Overall, the knowledge of complications and their risk factors was low. Bleeding and perforation were the most commonly recognized complications for both colonoscopy and UGIE. A lower perceived risk of UGIE complications was significantly associated with a higher willingness to undergo UGIE combined with a screening colonoscopy. Moreover, among respondents who have already undergone endoscopic screening, those who underwent combined screening reported a lower complication risk perception, along with a heightened awareness of potential complications.

Complication risk perception has been scarcely characterized in Western countries, with research primarily focusing on complications associated with colonoscopy [9, 13]. A US cross-sectional study, targeting patients scheduled for a screening colonoscopy, evaluated patient's understanding of the procedure's benefits, risks, and alternatives [14]. A total of 48% described at least one risk of the procedure, and only 3% described the minimal required elements for informed consent. King-Marshall et al. [15] conducted a study evaluating patient and caregiver understanding of the colonoscopy procedure and confirmed that 27% of patients provided an incorrect or vague definition of colonoscopy and only 2% provided a definition that correctly detailed the procedure characteristics and purpose. The notably low knowledge of complications associated with endoscopic screening

Table 3. Perceived risk of endoscopy-related complications

	Total (N = 217)	Never-screened (N = 92)	Endoscopically screened (N = 125)	p value
<i>Colonoscopy</i>				
Perceived complication risk, median (IQR)	1 (1–3)	1 (1–2)	1 (1–3)	0.034
High risk ^a , n (%)	68 (34)	16 (19)	52 (45)	<0.001
Did not know any complication, n (%)	133 (61)	89 (97)	44 (35)	<0.001
Complication knowledge score (1–7), median (IQR)	2 (1–2)	1 (1–1)	2 (1–2)	0.129
Complication knowledge score ≥2, n (%)	43 (20)	0 (0)	43 (34)	<0.001
Did not know any risk factor, n (%)	194 (90)	91 (99)	103 (83)	<0.001
Risk factor knowledge score (1–12), median (IQR)	1 (1–2)	1 (1–1)	1 (1–2)	0.727
Risk factor knowledge score ≥2, n (%)	6 (3)	0 (0)	6 (5)	0.032
<i>UGIE</i>				
Perceived complication risk, median (IQR)	1 (1–3)	1 (1–1)	1 (1–3)	0.016
High risk ^b , n (%)	56 (29)	12 (14)	44 (41)	<0.001
Did not know any complication, n (%)	181 (83)	92 (100)	89 (71)	<0.001
Complication knowledge score (1–7), median (IQR)	2 (1–2)		2 (1–2)	
Complication knowledge score ≥2, n (%)	21 (10)	0 (0)	21 (17)	<0.001
Did not know any risk factor, n (%)	211 (97)	91 (99)	120 (96)	0.196
Risk factor knowledge score (1–12), median (IQR)	1 (1–2)		1 (1–2)	
Risk factor knowledge score ≥2, n (%)	1 (1)	0 (0)	1 (1)	0.579

IQR, interquartile range; SD, standard deviation; UGIE, upper gastrointestinal endoscopy. ^aAnswered “agree” or “strongly agree” to “Colonoscopy may be harmful to the body (e.g., bowel perforation)”. ^bAnswered “agree” or “strongly agree” to “UGIE may be harmful to the body”.

procedures, as identified in our sample, reinforces the need for additional efforts to increase health literacy in the general population. It is essential to strengthen the interaction between individuals scheduled for endoscopic screening procedures, their close relatives, and healthcare professionals, particularly primary care physicians, gastroenterologists, and nurses. This increased engagement is pivotal to ensuring thorough communication regarding the potential complications associated with these procedures. By fostering a more robust dialogue, healthcare professionals can provide a comprehensive explanation of the associated risks and benefits, thereby promoting informed decision-making and addressing any concerns raised by patients or their relatives.

A prospective US study evaluated risk perception facing the scenario of unwillingness to undergo a screening colonoscopy due to fear of suffering a complication and reported a higher perceived risk of complications from colonoscopy in never-screened respondents (38%) as opposed to in previously screened participants (19%) [9]. In Germany, where the CRC screening program has offered colonoscopy as primary

screening method since 2002 [16], a cross-sectional study concluded that concerns about colonoscopy were independent predictors of compliance with screening recommendations [17]. In the latter study, 36% (95% CI: 28.1–44.3) of the non-screened versus 7.8% (95% CI: 2.6–13.0) of the screened group reported to be afraid of complications caused by colonoscopy [17]. In contrast, our results show that never-screened participants have a lower perceived risk of colonoscopy complications and suggest that the perceived risk of complications may not be a determining factor for CRC screening uptake. Nonetheless, the observed difference in complication risk perception may be explained by the fact that individuals who had previously undergone endoscopic screening were instructed to read the informed consent form prior to the endoscopic procedure and received clarification regarding the potential complications. Never-screened participants were not exposed to the informed consent process that is required prior to endoscopic screening. However, exposure to health literacy campaigns, discussions of endoscopic procedures during primary care appointments, or

contact with relatives or acquaintances who had undergone such procedures may have influenced their perception of the risk of complications. However, even among respondents who underwent colonoscopy and had previously been exposed to informed consent, knowledge of complications and their risk factors was suboptimal. Improving risk perception and knowledge of complications associated with endoscopic screening procedures presents an opportunity to boost adherence rates and reduce the burden of medicolegal litigation.

A systematic review on barriers and facilitators to GC screening, including mostly Eastern studies, concluded that fear of the screening procedure was the most commonly reported barrier [18]. Fear of undergoing UGIE was pointed out as the reason for nonadherence by 38.1% of participants in a cross-sectional Chinese study and by 8.4% in the Korean National Cancer Screening Survey [19–21]. As previously reported, a lower perception of the negative health consequences of UGIE was independently associated with a higher intention to undergo combined screening [22]. Our results reinforce the impact of complication risk perception in the acceptance of combined screening.

To our knowledge, this is the first European study to simultaneously measure the risk perception of endoscopic-related complications for both colonoscopy and UGIE in a screening setting. Utilization of the previously validated PERCEPT-PREVENT tool enabled an objective assessment of risk perception [12].

Our study presents some limitations. The presented results rely on measures susceptible to bias, including selective memory, social desirability, or attribution bias. Notably, respondents who underwent endoscopic screening procedures were recently informed about the potential complications, which may explain the higher knowledge scores obtained. The impact of complication risk perception in CRC screening uptake may have been underestimated since individuals who tested negative for FOBT, as well as FOBT-positive individuals who either declined screening colonoscopy or were waiting for its scheduling, were excluded. Details on colonoscopy completeness (including reasons for incomplete procedures), the number of previous endoscopic procedures, and any history of colonoscopy-related complications, which could affect the perception of complication risk, were not retrieved. Furthermore, the survey primarily was conducted regionally rather than nationally.

Further prospective, nationwide studies are necessary to confirm our findings, especially through the application of the survey before and after an educational program. Measuring the perceived risk of complications could extend beyond the screening context to other therapeutic endoscopic procedures, with the adaptation of the PERCEPT-PREVENT tool for high-risk procedures offering valuable

insights, particularly regarding medicolegal concerns. Moreover, educational campaigns focused on complication risk perception should be integrated at the primary care level and disseminated through social media and other communication platforms. Having primary care physicians initiate the informed consent process by explaining the procedure, along with establishing direct communication channels for patients to connect with healthcare providers at endoscopy units to address specific concerns, could further enhance their understanding of the associated risks.

Acknowledgments

Gastroenterology nurses Cláudia Rocha and Cátia Ribeiro conducted the telephone interviews.

Statement of Ethics

This study protocol was reviewed and approved by the Ethical Committees of the 3 institutions involved in the study, namely, *Administração Regional de Saúde do Norte (ARSN)*, *Unidade Local de Saúde Gaia Espinho*, and *Instituto Português de Oncologia do Porto*. Since the regional CRC screening program is performed and operationalized by ARSN, this organization provided random telephonic contacts of participants, after Data Protection Committee's approval. The questionnaire was applied through telephonic interview, and informed verbal consent was obtained from all participants after explanation of aims of the study.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This research received a 3-year research grant from *Sociedade Portuguesa de Endoscopia Digestiva*. The funder had no role in the design, data collection, data analysis, and reporting of this study.

Author Contributions

Mário Dinis-Ribeiro, Diogo Libânio, and João Carlos Silva designed the study. João Carlos Silva and Diogo Libânio performed the research and analyzed the data. Fernando Tavares, Mário Dinis-Ribeiro, and Diogo Libânio revised the paper for critically important intellectual content.

Data Availability Statement

All data generated or analyzed during this study are included in this article and its supplementary material files. Further inquiries can be directed to the corresponding author.

References

- Feld KA, Feld AD. Risk management and legal issues for colonoscopy. *Gastrointest Endosc Clin N Am*. 2010;20(4):593–601. <https://doi.org/10.1016/j.giec.2010.07.002>
- Oh HM, Cha JM, Shin S, Park J, Cho D, Choi S. Medico-legal implications for the colon perforation during colonoscopy. *J Forensic Leg Med*. 2021;80:102185. <https://doi.org/10.1016/j.jflm.2021.102185>
- Saftoiu A, Hassan C, Areia M, Bhutani MS, Bisschops R, Borjes E, et al. Role of gastrointestinal endoscopy in the screening of digestive tract cancers in Europe: European society of gastrointestinal endoscopy (ESGE) position statement. *Endoscopy*. 2020;52(4):293–304. <https://doi.org/10.1055/a-1104-5245>
- Cardoso R, Guo F, Heisser T, Hoffmeister M, Brenner H. Utilisation of colorectal cancer screening tests in European countries by type of screening offer: results from the European health interview survey. *Cancers*. 2020;12(6):1409. <https://doi.org/10.3390/cancers12061409>
- Shaukat A, Kahi CJ, Burke CA, Rabeneck L, Sauer BG, Rex DK. ACG clinical guidelines: colorectal cancer screening 2021. *Am J Gastroenterol*. 2021;116(3):458–79. <https://doi.org/10.14309/ajg.0000000000001122>
- Ferlay J, Steliarova-Foucher E, Lortet-Tieulent J, Rosso S, Coebergh JWW, Comber H, et al. Cancer incidence and mortality patterns in Europe: estimates for 40 countries in 2012. *Eur J Cancer*. 2013;49(6):1374–403. <https://doi.org/10.1016/j.ejca.2012.12.027>
- Libanio D, Antonelli G, Marijnissen F, Spaander MC, Hassan C, Dinis-Ribeiro M, et al. Combined gastric and colorectal cancer endoscopic screening may be cost-effective in Europe with the implementation of artificial intelligence: an economic evaluation. *Eur J Gastroenterol Hepatol*. 2024;36(2):155–61. <https://doi.org/10.1097/MEG.0000000000002680>
- Areia M, Spaander MC, Kuipers EJ, Dinis-Ribeiro M. Endoscopic screening for gastric cancer: a cost-utility analysis for countries with an intermediate gastric cancer risk. *United Eur Gastroenterol J*. 2018;6(2):192–202. <https://doi.org/10.1177/2050640617722902>
- Harewood GC, Wiersma MJ, Melton LJ 3rd. A prospective, controlled assessment of factors influencing acceptance of screening colonoscopy. *Am J Gastroenterol*. 2002;97(12):3186–94. <https://doi.org/10.1111/j.1572-0241.2002.07129.x>
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet*. 2007;370(9596):1453–7. [https://doi.org/10.1016/S0140-6736\(07\)61602-X](https://doi.org/10.1016/S0140-6736(07)61602-X)
- Monteiro H, Tavares F, Reis J, Ferreira G, Campos MJ, Costa S, et al. Colorectal screening program in northern Portugal: first findings. *Acta Med Port*. 2022;35(3):164–9. <https://doi.org/10.20344/amp.15904>
- Silva JC, Santos C, Dinis-Ribeiro M, Libanio D. Development and validation of the PERCEPT-PREVENT tool to determine risk perception and attitudes towards digestive cancer screening. *Eur J Gastroenterol Hepatol*. 2024;36(1):45–51. <https://doi.org/10.1097/MEG.0000000000002671>
- Tarr G, Smith RA, John RA, Crowley AP, Kok JBC, Lee HN, et al. Perceived risks and benefits of surveillance colonoscopy in people undergoing surveillance for family history of colorectal cancer. *N Z Med J*. 2013;126(1382):58–69.
- Schwartz P, Edenberg E, Barrett PR, Perkins SM, Meslin EM, Imperiale TF. Patient understanding of benefits, risks, and alternatives to screening colonoscopy. *Fam Med*. 2013;45(2):83–9.
- King-Marshall EC, Mueller N, Dailey A, Barnett TE, George TJ Jr, Sultan S, et al. “It is just another test they want to do”: patient and caregiver understanding of the colonoscopy procedure. *Patient Educ Couns*. 2016;99(4):651–8. <https://doi.org/10.1016/j.pec.2015.10.021>
- Guo F, Chen C, Schöttker B, Holleczer B, Hoffmeister M, Brenner H. Changes in colorectal cancer screening use after introduction of alternative screening offer in Germany: prospective cohort study. *Int J Cancer*. 2020;146(9):2423–32. <https://doi.org/10.1002/ijc.32566>
- Ziegler M, Schubring-Giese B, Bühner M, Kolligs FT. Attitude to secondary prevention and concerns about colonoscopy are independent predictors of acceptance of screening colonoscopy. *Digestion*. 2010;81(2):120–6. <https://doi.org/10.1159/000223448>
- Hatamian S, Etesam S, Mazidimoradi A, Momenimovahed Z, Salehiniya H. The barriers and facilitators of gastric cancer screening: a systematic review. *J Gastrointest Cancer*. 2021;52(3):839–45. <https://doi.org/10.1007/s12029-021-00652-8>
- Liu Q, Zeng X, Wang W, Huang RL, Huang YJ, Liu S, et al. Awareness of risk factors and warning symptoms and attitude towards gastric cancer screening among the general public in China: a cross-sectional study. *BMJ Open*. 2019;9(7):e029638. <https://doi.org/10.1136/bmjopen-2019-029638>
- Park B, Lee HY, Choi KS, Lee YY, Jun JK, Park EC. Cancer screening in Korea, 2010: results from the Korean national cancer screening survey. *Asian Pac J Cancer Prev*. 2011;12(8):2123–8.
- Shin JY, Lee DH. Factors associated with the use of gastric cancer screening services in Korea: the fourth Korea national health and nutrition examination survey 2008 (KNHANES IV). *Asian Pac J Cancer Prev*. 2012;13(8):3773–9. <https://doi.org/10.7314/apjcp.2012.13.8.3773>
- Silva JC, Dinis-Ribeiro M, Tavares F, Libanio D. Gastric cancer screening: intention to adhere and patients’ perspective. *Heliobacter*. 2024;29(5):e13135. <https://doi.org/10.1111/hel.13135>