# Colorectal cancer screening challenges in a central Saudi Arabia: 1 st round results

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**Research Article**

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# Abstract

**Purpose:**

There is no national policy for colorectal cancer (CRC) screening in Saudi Arabia (SA) despite the increasingly early onset of CRC in high-income countries. This study aims to assess the participation and impact of a CRC screening program in central area of Saudi Arabia.

**Methods:**

The guaiac fecal occult blood test (g-FOBT) was used as a first-line, non-invasive screening test to select patients for colonoscopy. The g-FOBT (+) Saudis, aged 45–76 years old (yo), were provided colonoscopies regardless of their risk of developing CRC or the presence of symptoms.

**Results:**

The first-round participation rate was 73% (35640/48897). The average age was 53 yo (range 45-75), 49% were female (17464/35640), 76% were asymptomatic, 13% underwent sigmoidoscopy, and 77% were well-prepared**.** The g-FOBT (+) rate was 6.3% (n = 2245), and 76% (n = 1701) of these underwent lower GI endoscopy. The prevalence of CRC was 4.8% (81/1701), advanced adenoma 9.5% (162/1701), adenoma 15.9% (270/1701), non-adenoma polyps 7.9% (135/1701), and no polyps or tumors 25.4% (432/1701). Other findings were internal hemorrhoids 32% (60/1701), colitis 24% (45/189), diverticulosis 7.9% (135/1701), and diverticulitis 2.6% (27/1053). Among young people volunteers CRC incidence was high, 1/3 of those with CRC with female predominance, above age 50 volunteers with CRC were more likely male, had older age, and among all CRC was at the left site colon ($p < 0.005$) during endoscopy.

**Conclusions:**

Low numbers of advanced adenomas and cancers were detected in the first round of CRC screening, however early onset CRC is rising. Screening participation was low, and public education is necessary along with expanded colonoscopy resources.


# 1. Introduction

Colorectal cancer (CRC) is the third most common cancer worldwide. In the U.S. and most western European countries, CRC is the second leading cause of cancer-related death [1, 2]. In Saudi Arabia (SA), CRC is the second-most common reported malignancy [3, 4] ranking first among men (10.6%) and third among women (8.9%) [5]. The incidence of CRC has increased recently among young people (< 50 years) [6, 7]. The underlying reasons are unknown but likely include Inflammatory Bowel Disease, obesity, tobacco use, physical inactivity, red and process meat consumption, inappropriate diet such as high fructose corn syrup, microbiome changes from antibiotic use, radiation exposure, epidemics, and genetic abnormalities such as germline mutations [8]. One in five young patients with CRC carries a mutation associated with cancer predisposition [9]. Population-based registries from high-income countries such

as Australia, Canada, Denmark, Norway, New Zealand, Ireland, and United Kingdom show that among people aged 50–74 years old (yo), the incidence of CRC is decreasing and increasing among 20–29 year-olds [10]. Similar in Saudi Arabia, a retrospective study between 2001–2016 using Saudi National Registry showed similar trends decrease in late onset CRC and increase in early onset CRC [6] as well in the Northern region of the country [7]. Further research is required to establish the causes of this phenomenon so that preventive and early-detection strategies can be implemented.

In the past, the Saudi Cancer Registry (http://www.scr.org.sa/) indicated a rise in CRC frequency from 2001 to 2006 to twice the incidence observed from 1994 to 2001 [11] but no data was available assessing the trend in early-onset CRC. Usually, once diagnosed young Saudis present with advanced-stage CRC and poor outcome [3, 7] and are diagnosed at a younger age as recently described in Western countries [12, 13]. However, SA has no nation-wide strategy for CRC screening although well-established increasing incidence in Saudis under 50 yo that reflects the 85% of the population [7, 14, 15].

The global interest is that the CRC become the most common early onset CRC death [16]. Clinical practice guidelines for CRC have been published in SA since 2015 [17]. The authors target asymptomatic people with an average-risk for CRC in the general Saudi population for CRC screening. They suggest that screening should start at the age of 45 to 70 years. Colonoscopy is the “gold standard” of CRC screening and is recommended every 10 years. An alternative to colonoscopy—sigmoidoscopy screening—is recommended every five years. Scope-based practices can be combined with a fecal immunochemical test (FIT) annually or every three years without an annual FIT.

In Europe, although it varies by country, screening with a FIT for hemoglobin and the guaiac-based fecal occult blood test (g-FOBT) are considered preventive measures, and screening programs should use both the g-FOBT and sigmoidoscopy. In few other countries, colonoscopy is the follow-up for subjects with positive g-FOBT results. Screening should start for everyone between 50 to 74 years old in 1-2-year intervals [18, 19].

The European Union's Advisory Committee on Cancer Prevention suggests that average-risk individuals be screened using the g-FOBT every 1–2 years, and colonoscopy is needed only for those with g-FOBT (+) tests [20].

Recently, updated guidelines published in USA including CRC screening in youger ages [16, 21, 22]. The USA guidelines [22] suggest adults aged more than 45–75 yo with an average risk of CRC undergo non-invasive screening using either a high-sensitivity stool-based test or an invasive diagnostic method such as structural (visual) examination (e.g., colonoscopy or sigmoidoscopy) and from 6–85 yo based on the individual’s preference. Subjects with positive non-invasive screening test results should undergo a timely colonoscopy. The options for CRC screening are: a) non-invasive tests (FIT annually, g-FOBT annually, and multi-genes panel stool DNA test every three years); and b) invasive tests (computed tomography colonography every 5 years, flexible sigmoidoscopy every 5 years, colonoscopy every 10 years and). In this study, we adopted a CRC-screening program for the general population in central region of SA, Riyadh province Al-Kharj, Riyadh the nation’s capital and most populous city.

## 2. Methods

# 2.1 Study design

We adopted a CRC screening program in Riyadh province Al-Kharj of Saudi Arabia. This was a population-based prospective study of people aged between 45 and 75 yo who were invited to participate in the CRCSP according to the updated AGA guidelines [22] for CRC screening from January 2017 to February 2022. Participants were identified prospectively via Public Health Registries. By February 2022, the first round of colonoscopy screening, slated for every three years, was completed. Those with a positive stool-based high-sensitivity g-FOBT underwent colonoscopies every year. We collected demographic details including residency on those subjects.

The study was conducted according to the STROBE statement. The Ethics Committee of PSAU University of Medical Sciences approved the study design, protocols, and informed consent procedure (PSAU/COM/RC/IRB/p/67).

Data from a database of endoscopy reports from participants in CRCSP were collected at the Endoscopy Unit of Prince Sultan Military Medical City, King Khaled Hospital and Prince Sultan Center for Health Care, Prince Sattam bin Abdulaziz University Hospital and Al Kharj Military Hospital.

# 2.2 Patients: inclusion and exclusion criteria

The inclusion criteria included individuals aged between 45–75 years old who can begin CRC screening at age 45. For people aged between 76 through 85, the screening decision is based on an individual's option considering comorbidities, life expectancy, and prior screening history.

The exclusion criteria were participants without accessible health records or who had moved out of Riyadh and Al-kharj during the observation period; people over 85 yo with blood in their stool at the interview; patients with previous CRC diagnosis, colonic resection, or any CRC chemotherapy or radiotherapy; colon disease such as colitis, diverticulitis, inflammatory bowel disease, or with an indication for polypectomy. Finally, individuals with a history of hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP), were excluded from the first non-invasive assessment. After recruitment, a checklist was completed by all patients, including age, sex, and family history of CRC.

# 2.3 Screening methods

# 2.3.1 Non-invasive assessment

Stool analysis used high sendistivy guaiac fecal occult blood test (HSgFOBT). Annual screening was usually recommended if the HSgFOBT test was negative. Those undergoing the HSgFOBT were instructed to avoid certain medications and food for several days before stool samples collected. The patients collected samples over three separate bowel movements. For each sample, the collected stool

was stored in a clean container provided by the lab. Lab analysis was performed according to the manufacturer's instructions from the HSgFOBT kit (Epitope Diagnostics Inc, USA).

### 2.3.2 Structural screening

Patients with positive g-FOBT results underwent the relevant scope-based evaluation. Endoscopic evaluation used lower gastrointestinal (GI) endoscopy (video-endoscope, GIF-160; Olympus Co., Tokyo, Japan) by a single experienced endoscopist.

## 2.4 Tissue sampling

Tissue was sampled only when necessary to confirm abnormal mucosal findings from the endoscopy. The samples were fixed in 10% formalin. Tissue samples labelled with the subject's identifier. A blinded pathologist used to analyze tissue samples to decrease measurement bias.

## 2.5 Statistics

Descriptive statistics were used to compare continuous variables. Data were presented in means, SD, and minimum and maximum values. Frequencies and interquartile ranges were used to present categorical variables. The t-test was used to analyze categorical variables, and the t-test was used for continuous variables. Multiple parameters were obtained from the data including demographics, investigations, and management. These were analyzed for statistical significance in the form of an endoscopic audit. The demographic information included the age, sex, and indication for lower GI endoscopy. P-values less than 0.05 were considered statistically significant.

# 3. Results

The CRCSP was implemented in early 2017. During these five years, 48,897 individuals were invited to participate according to inclusion and exclusion criteria in the CRC screening program established for outpatient clinics of family medicine and gastroenterology at four major hospitals: Prince Sultan Military Medical City, King Khaled Hospital and Prince Sultan Center for Health Care, Prince Sattam bin Abdulaziz University Hospital, and the Al Kharj Military Hospital. The first-round participation rate was 72.8% (35,640/48,897). The flow chart in diagram 1 shows the participants. The processing times for the first run are shown in Table 1. No complications were reported, and there were no cases of delayed colonoscopy.

Table 1
First-round processing times

| |
|---|
| • **Time until the g-FOBT result: 3.4 workdays** |
| • Time until intake: 11.2 workdays |
| • Time until colonoscopy: 13.4 workdays |
| • 6 weeks between participation and colonoscopy |

Of the 35,640 participants involved in the first round of the CRCSP, 2,245 had positive HSgFOBT results in the first non-invasive assessment used to prevent CRC. This translates into a HSgFOBT positivity rate of 6.3% (2,245 individuals positive), but only 1701 of these (76%) underwent a lower GI endoscopy. The rest refused due to invasiveness of the method, personal factors, travel, and health factors.

Of the 1701 patients who underwent the secondary assessment of structural screening for CRC (i.e., lower GI endoscopy), the average age was 58 yo (range 45–75) with approximately 60% (1026/1701) of subjects below 70 yo; 49% (837/1701) were female. All who underwent secondary assessment were asymptomatic without signs and symptoms of CRC: 13% (216/1701) had sigmoidoscopy due to intolerance to colonoscopy, and 77% (1323/1701) were well prepared.

The prevalence of CRC was 4.8% (81/1701) with advanced adenoma in 9.5% (162/1701), adenoma in 15.9% (270/1701), non-adenoma polyps in 7.9% (135/1701), and no polyps or tumors in 25.4% (432/1701) (Fig. 1). Other findings were internal hemorrhoids in 32% (540/1701), colitis in 24% (405/1701), diverticulosis in 7.9% (135/1701), and diverticulitis in 2.6% (27/1701). The distribution of endoscopic findings according to sex showed a significant male predominance ($p = 0.002$) (Fig. 2). The age distribution among the endoscopic findings showed a statistically significant predominance of CRC and advanced adenomas among individuals more than 50 yo ($p = 0.0001$) (Fig. 3). However, almost 1/3 (24 out of 81) of the subjects aged 45–50 yo showed early onset colorectal cancer with female predominance (16 out of 24, 66%) ($p = 0.001$). The total ASR was 3.2/100,000, for males 4.1/100,000 vesrus females 2.3/100,000The site distribution of CRC and polyps were significantly more frequently located in the left colon ($p = 0.004$) (Fig. 4).

# 4. Discussion

There are differences in CRC screening strategies due to differences in geographic variation of CRC prevalence, available funds, and health infrastructure [23, 24]. The impact and economic evaluations are great from early detection of CRC [25, 26]. However, many countries still lack effective CRC prevention and screening programs at the national level. Thus, the CRC screening program was implemented nation-wide in SA.

The CRCSP intends to help prevent CRC in central area of SA, Riyadh and its surrounding region Al-Kharj province of Riyadh—Riyadh the most populated area in SA. CRC screening programs using pure endoscopy and pathology are not appealing to a wide range of people because the method is invasive. This in turn leads to a lack of involvement. In our study, 20% of the subjects refused to undergo colonoscopy despite a positive HSgFOBT results. One recent study [28] reported that about 33% of scheduled colonoscopies were postponed during a period of 16 months because of encompassing personal, social, geographic, and health system factors. Here, the performance of colonoscopy was within two weeks: There was no delayed colonoscopy after the initial positive HSgFOBT becuase this delay was associated with poor outcomes due to CRC [29]. Second-round CRC screening will continue according to recommendations [16, 22].

In a local study, 71% of Saudis preferred CRC screening using the following modalities in descending order: CT colonography (CTC), stool based-test, colonoscopy, and flexible sigmoidoscopy [31]. Similar to our study results, there was a preference for HSgFOBT and then scope-based methods [31]. Furthermore, based on their investigation of CRC awareness among healthy individuals in SA, Zubaidi et al. strongly recommended implementing a countrywide policy including an education/screening program to improve CRC knowledge [4]. Reasons included misconceptions regarding universally-accepted screening protocols, atypical symptoms, and awareness of CRC disease in SA in general.

There is a lack of national data in the literature from SA on the frequency of adenomatous polyps and the age groups most affected. The prevalence of CRC in our study was 4.8%, advanced adenoma was 9.5%, adenoma was 15.9%, non-adenoma polyps was 7.9%, and no polyps or tumors was 25.4%.

Another retrospective cohort study reported adenomas at 8.1% and advanced adenomas at 0.5% [26]. Most adenomas (33.9%) were located on the left side of the colon. Similar results have been reported in a retrospective study reporting that 25% of the patients diagnosed with rectal tumors and the majority 42.89% with left colon [32].

In this screening study, the Saudi population has a mean age of 50.5 ± 15.9 yo with a female predominance of 57.7%. Higher frequencies relative to our study were expected because our study involved a general population being screened for CRC.

A recent retrospective study from 2009 to 2017 reported a significant increase in the incidence of late onset CRC between 2009 and 2011 (28.46%) and 2012–2014 (35.47%); folloed by a drop from 2015 to 2017 to be 32.51% [32].

In other studies there is a decrease of late onset cancer at ages more than 50 years old [33]. In our study the total ASR was 3.2/100,000, for males 4.1/100,000 vesrus females 2.3/100,000. Compare with an older study at 2004 [33], the highest ASR were much higher Riyadh region 9.6/100,000. Other areas with high ASR were in Eastern regioon 9.8/100,000, Northern region 9.6/100,000, Makkah region at 7.4/100,000 and Tabuk region 8.2/100,000.. The median age at diagnosis was 60 years among males with age between 19–105 and 58 years among females with age between 16–100 years. The ASR has decreased in ages more than 50 years old but early onset cancer is still much lower than in developed countries in contrary to our recent updated findings after 2017..

A meta-analysis of six observational studies reported that there is low-quality evidence of colonoscopy referring to 34 serious complications per 100,000 CRC screening procedures. In particular, 2.8 serious complications per 1,000 were reported for colonoscopy including perforation, bleeding, and even death. The authors concluded that invasive CRC screening modalities should only be undertaken at specilazed centers with skillful and experienced clinical staff for advanced therapeutic endoscopy. However, no complications were reported in our study.

The first round of non-invasive assessment using the g-FOBT highlighted the strength and weakness of current clinical practices: the low number of referrals for CRC, the use of a non-invasive CRC screening test, and the unwillingness of HSgFOBT (+) individuals to proceed to structural tests; there was a low participation in SA relative to the international guidelines [22]. The high number of referral of patients at risk for CRC for endoscopy provided by local endoscopy services in the Al Kharj area combined with the second structural screening for CRC will decrease the incidence of CRC in Al Kharj by detecting premalignant and early stage cancers sufficiently before they grow to advanced. The outcome of CRC strongly depends on the stage at which it is detected; thus, those at risk for CRC must be motivated to undergo endoscopy.

The weakness of this study is that it was conducted to adopt the CRCSP in a large area of Riyadh province Al-Kharj, the capital of SA, but this approach is not yet a part of a national policy study for CRC screening. The sample size is small, but there is no limitation in applying the program in more hospitals in Riyadh for larger numbers of participants over a longer period after public education. Other limitations to be considered is the survivor cancer care and availability of molecular characterization of tumors and testing necessary to improve the outcomes of young patients with CRC. The assessment of patient-level information such as education, income, obesity, physical activity, was not performed because our analysis was based on aggregate data but still useful for assessing cancer rate trend.

One of the strengths of our data that there is no prospective study to assess the trends in CRC incidence frequencies among the young Saudi < 50 yo representing the 85% of the population. Our study showed low rates in CRC from 2017–2021 versus earlier years; there is no data available after 2016. The decrease in incidence frequencies could be possible attributed to the utility CRC cases in registries of other studies vs. the policy of population-based CRC screening since the initial CRC guidelines published in 2015. There is a high incidence in early onset CRC as reported in other studies with female predominance. One study was from northern area of Saudi Arabia although the study is retrospective and the sample represented all available colorectal cancers during a period of ten years.[7] and one also retrospective from Saudi National Registry before 2016 [6]. Our study reflects the global concern of early-onset CRC [16] with poor outcomes [34].

In conclusion, we detected a low incedence of CRC and advanced adenomas in the first round of CRC screening, thus highlighting a fall in CRC incidence in late onset CRC but an increase in early onset cancer. Participation in CRC screening was low. Subsequently, public education program is highly recommened along with endsocpy resources.

# Declarations

### Disclosure statement

The authors have no potential conflicts of interest related to this article.

### Author contributions

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**Additional information**

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# Figures

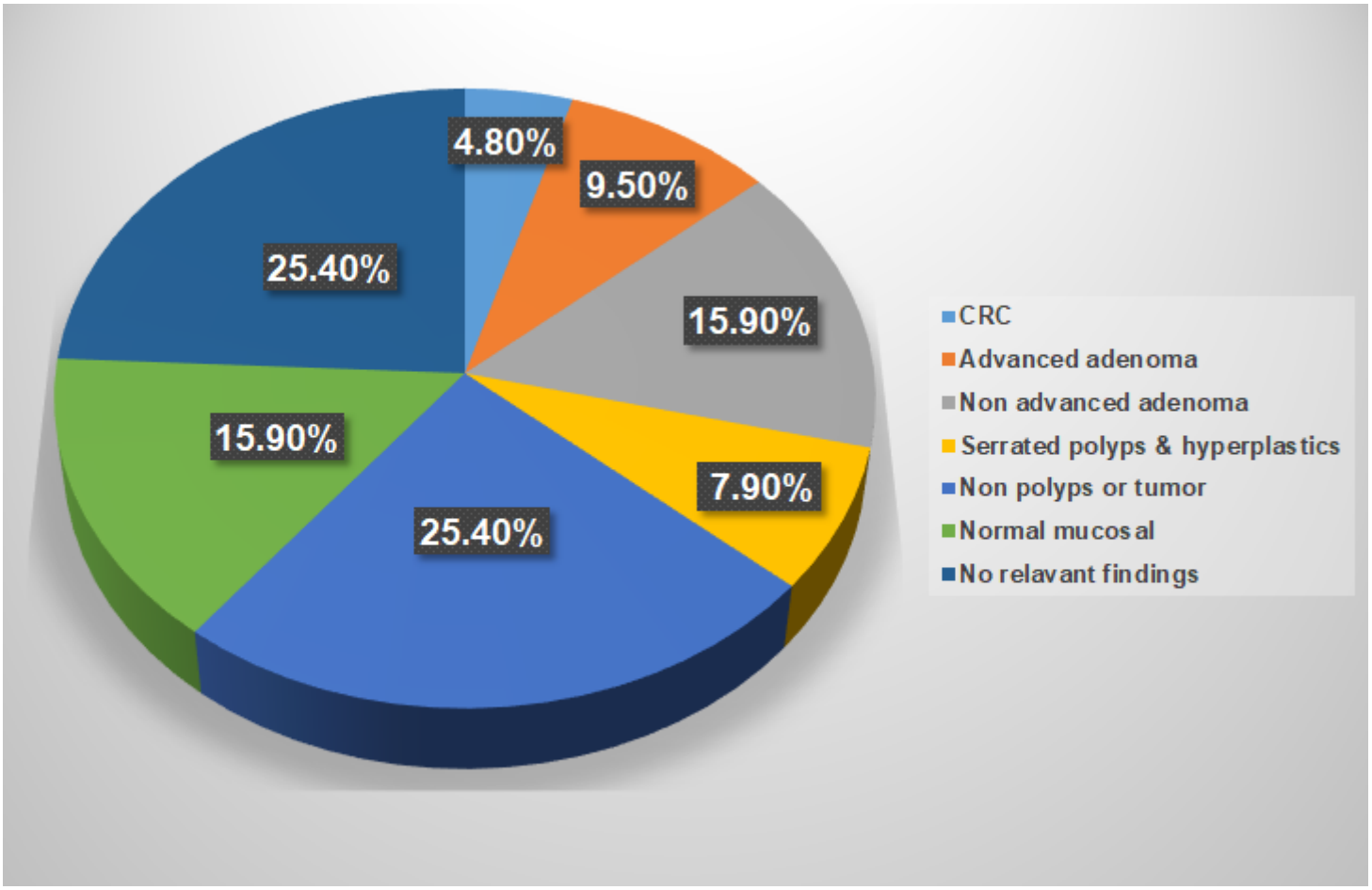


**Figure 1**

Frequency distribution of the endoscopy findings.

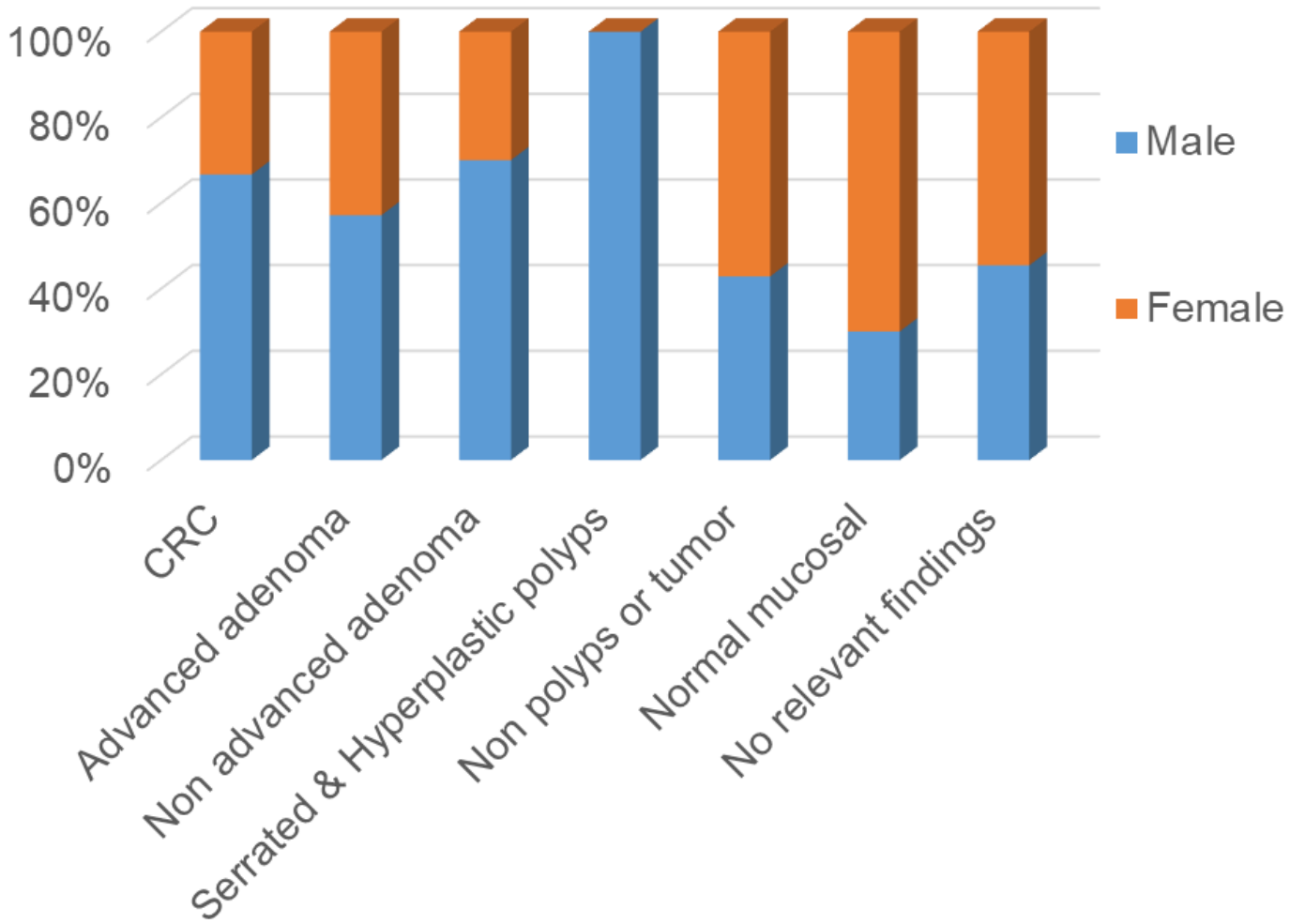


**Figure 2**

Gender distribution of the endoscopy findings.

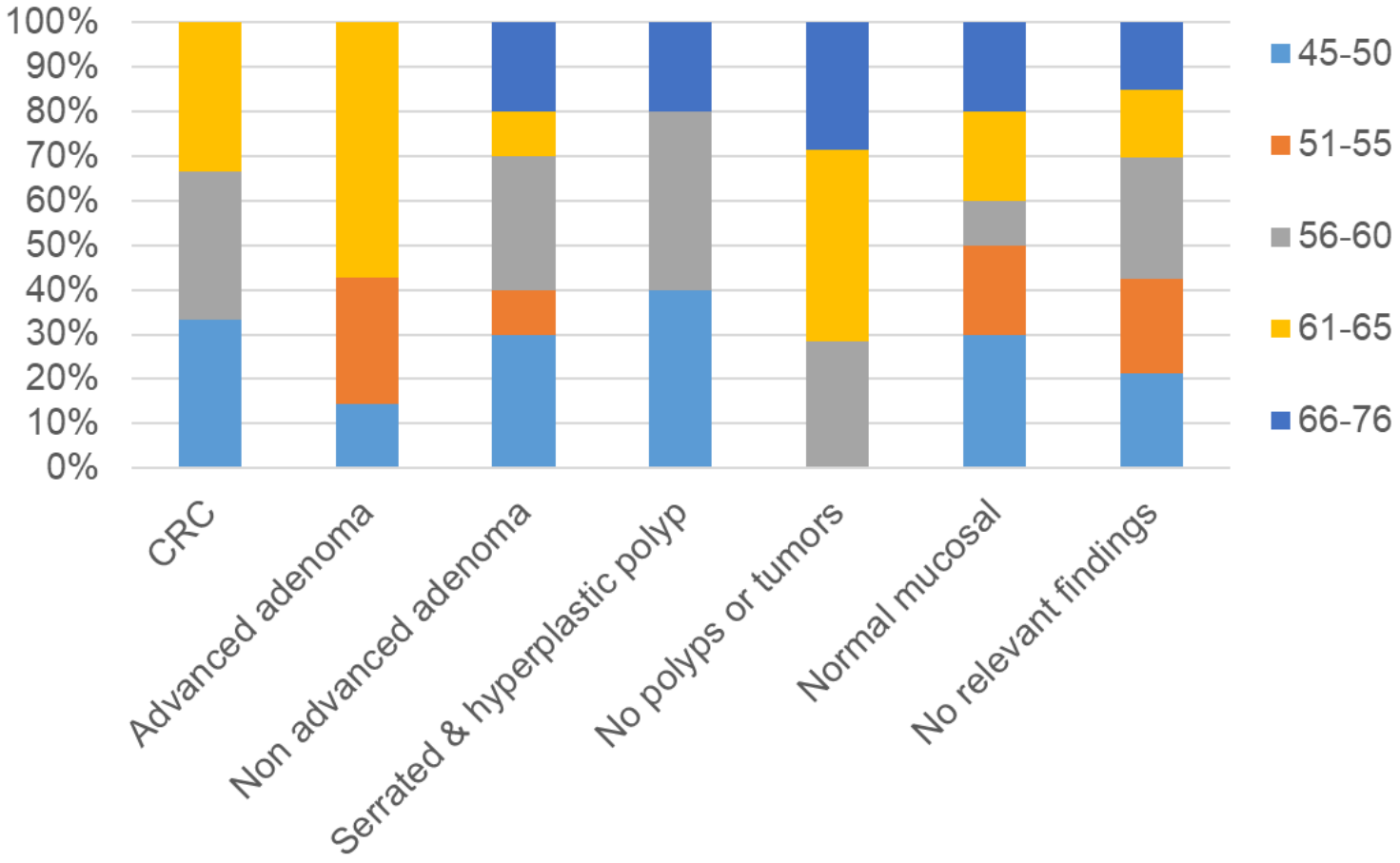


**Figure 3**

Age distribution of the endoscopy findings.

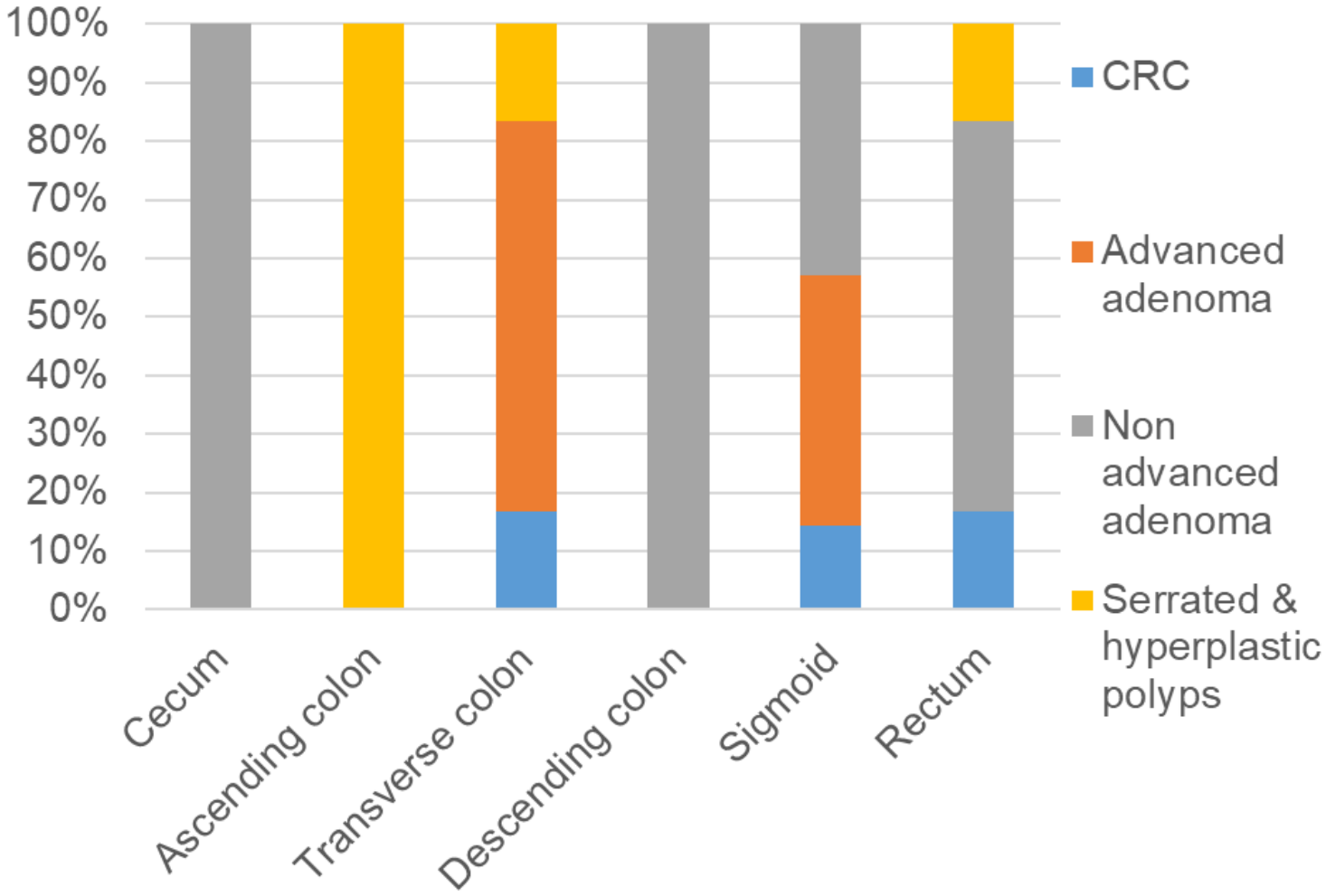


**Figure 4**

Site distribution of the endoscopy findings.

## Supplementary Files

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- chart.png