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ORIGINAL ARTICLE

Surgical complications in a population-based colorectal cancer screening program: Incidence and associated factors

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Colorectal cancer;
Screening;
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Complications

Abstract
Introduction: Colorectal cancer (CRC) screening programs produce risks, including those derived from colorectal surgeries. The objective of this analysis is to evaluate the complications associated with the surgery.
Patients and methods: Retrospective analysis including patients who required colorectal surgery within the population-based CRC screening program in Galicia (May 2013–June 2019). We analyzed the indication for surgery and the rate of in-hospital (mild I-II, severe III-V, Clavien-Dindo classification) and at discharge complications. We performed a multivariate analysis to determine the variables independently associated.
Results: In the analyzed period, 1092 patients underwent surgery (benign lesion 16.5%, pT1 CRC 18.2%, rest of CRC 64.6%) laparoscopic approach in 69.8% of the cases. In-hospital complications were detected in 19.2% of patients (mild: 13.4%, severe: 5.9%, deaths: 0.2%) and at discharge in 159 (14.6%) patients. Male sex was associated with in-hospital complications (OR 2.0 95% CI 1.3—3.0). The variables associated with severe complications were: male sex (OR 2.6, 95% CI 1.2—5.5), tertiary hospital (OR 0.5, 95% CI (0.2—0.9) and ECOG I (OR 0.2, 95% CI 0.05—0.6). The factors associated with complications after discharge were age ≥60 years (OR 1.5, 95% CI 1.0–2.3), rectal location (OR 1.6, 95% CI 1.1–2.3) and in-hospital complications (OR 2.2, 95% CI 1.5–3.2).

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Conclusions: Surgery is the main cause of morbidity and mortality associated with a CRC screening program. These results must be taken into account in the decision making of lesions that are candidates for endoscopic resection.

PALABRAS CLAVE
Cáncer colorrectal;
Cribado poblacional;
Cirugía;
Complicaciones

Complicaciones posquirúrgicas en un programa de cribado poblacional de cáncer colorrectal: incidencia y factores asociados

Resumen
Introducción: Los programas de cribado de cáncer colorrectal (CCR) producen riesgos, entre ellos los derivados de las cirugías colorrectales. El objetivo de este análisis es evaluar las complicaciones asociadas a la cirugía.
Pacientes y métodos: Análisis retrospectivo de los pacientes que requirieron cirugía colorrectal dentro del programa poblacional de cribado de CCR de Galicia (mayo de 2013-junio de 2019). Analizamos laindicación de la cirugía y la tasa de complicaciones intrahospitalarias (leves I-II, graves III-V, clasificación Clavien–Dindo) y al alta. Determinamos mediante un análisis multivariante las variables asociadas a su aparición.
Resultados: En el periodo analizado, 1092 pacientes fueron intervenidos (lesión benigna 16.5%, CCR pT1 18.2%, resto CCR 64.6%), por vía laparoscópica en el 69.8% de los casos. Se detectaron complicaciones intrahospitalarias en el 19.2% de los pacientes (leves: 13.4%, graves: 5.9%, fallecimientos: 0.2%) y al alta en 159 (14.6%) pacientes. El sexo masculino se asoció a las complicaciones intrahospitalarias (OR 2.0 IC 95% 1.3—3.0). Las variables asociadas a las complicaciones graves fueron: sexo masculino (OR 2.6, IC 95% 1.2—5.5), hospital terciario (OR 0.5, IC 95% (0.2—0.9) y ECOG I (OR 0.2, IC 95% 0.05—0.6). Los factores asociados a las complicaciones tras el alta fueron edad ≥60 años (OR 1.5, IC 95% 1.0–2.3), la ubicación rectal (OR 1.6, IC 95% 1.1–2.3) y complicaciones intrahospitalarias (OR 2.2, IC 95% 1.5–3.2).
Conclusiones: La cirugía es la principal causa de morbimortalidad asociada a un programa de cribado de CCR. Estos resultados deben ser tenidos en cuenta en la toma de decisiones en lesiones candidatas a resección endoscópica.

Introduction

Colorectal cancer (CRC) is a highly prevalent disease in our society, with a known natural history that permits early detection and reduced associated mortality. For this reason, it is a condition that benefits from population screening to detect precancerous lesions or early-stages tumours.[1] The effectiveness of the different CRC screening programme options (stool tests, sigmoidoscopy, colonoscopy) in reducing the mortality and incidence of CRC has been demonstrated both in clinical trials and in systematic reviews.[2,3]

In screening programmes, the benefit obtained must outweigh any harm, caused, for example, by overdiagnosis, overtreatment, false positives, false security, incidental findings or complications.[4] Although the complications associated with diagnostic tests are well described in CRC screening,[1,5] there is no such certainty regarding overdiagnosis and overtreatment. Overdiagnosis is defined as the diagnosis of a medical condition or illness that would not cause symptoms or death during a patient's lifetime. In the case of CRC screening, the treatment of non-invasive CRC and overdiagnosed polyps may be regarded as overtreatment.[6]

The endoscopic resection of colorectal polyps is the key to reducing the incidence and mortality of CRC.[7] Although the side effects are limited, mainly post-polypectomy syndrome, rectal bleeding and perforation, they are responsible for the majority of colonoscopy-related complications.[1] Endoscopic resection removes up to 90% of advanced complex polyps.[8] However, the introduction of CRC screening programmes has increased the number of colectomies for benign polyps. In the United States, up to 25% of colectomies are performed for non-malignant polyps.[9] Related in-hospital mortality and morbidity have reached 0.8% and 25.3%, respectively.[10]

There is scant evidence available on the risks associated with surgery in a CRC screening programme. For this reason, we decided to conduct an observational study to evaluate the complications associated with surgery as well as the factors associated with these complications in a CRC population screening programme.

Material and methods

Study design

Cross-sectional retrospective study in which all patients who required colorectal surgery after a colonoscopy performed within the CRC population screening programme as of its launch in May 2013 until June 2019 were included.

Description of the CRC population screening programme in Galicia

The CRC population screening programme in Galicia is based on the performance of a biennial immunological test for the detection of faecal occult blood (FOB) with a cut-off point of 20 μg of haemoglobin/g of faeces in subjects aged between 50 and 69 years. Between its launch in June 2013 and until July 2019, 721,349 people were invited to participate in the screening programme. The programme was started in the health areas of Ferrol in 2013, Ourense in 2015, Pontevedra, Santiago and Lugo in 2016, and A Coruña and Vigo in 2017. The screening programme is coordinated by the Department of Public Health of the Regional Ministry of Health, which is in charge of identifying the subjects, inviting them to participate, receiving the results of the FOB test and summoning patients with a positive result for follow-up.[11]

Database

Patients with colorectal surgery were identified in the information system of the CRC screening population programme in Galicia. Surgery was confirmed by consulting the unified electronic medical record (IANUS) of the Galician Health Service.

Variables collected

Data were collected on demographics (age and sex), the result of the FOB test, anaesthetic risk and quality of life data measured by the *American Society of Anesthesiologists*(ASA) and *Eastern Cooperative Oncology Group* (ECOG) scales and the level of specialisation at the hospital where the patient underwent surgery. The following surgery-specific data were identified: type of surgery, location of the lesion, neoadjuvant treatment performed, surgical approach, duration of admission, complications during admission and after discharge and survival at the time of the analysis. To classify the severity of complications during the hospital stay, we used the Clavien–Dindo classification,[12] considering those classified as grades I-II as mild, those requiring reoperation as grade III, those requiring admission to a critical care unit as grade IV and patient deaths as grade V. Complications were defined as minor for grades I-II and major for grades III-V.

Statistical analysis

First, a descriptive analysis of the subjects included was performed. We used the median and interquartile range for quantitative variables and the absolute number and frequency for qualitative variables. We determined which variables were associated with the appearance of both overall and major complications during admission and after discharge. Initially, we carried out a univariate analysis using the chi-square test for qualitative variables and Student's t-test for quantitative variables. Statistically significant or clinically relevant variables were included in a logistic regression. Associations were expressed as *odds ratio* (OR) with the 95% confidence interval (CI). The statistical analysis was performed using the statistical package IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, USA; IBM Corp.

Ethical considerations

The study was authorised by the Clinical Research Ethics Committee of Galicia (2018/593). Since the study was based on a database analysis, informed consent was not required. The information was accessed in accordance with current Spanish and European legislation.

Results

Description of the sample and surgeries

In the period analysed, we identified 1,092 patients participating in the CRC screening population programme who required surgical treatment. Only three patients underwent surgery outside the Galician Health Service and for whom no surgery-related information could be retrieved. The epidemiological data of the patients included in the study are shown in Table 1. The surgical patients were predominantly male (66.3%) aged over 60 years (72%), with a faecal haemoglobin concentration higher than 200 μg/g of faeces in 42.4% of patients, a low pre-anaesthetic risk (ASA I) in 60.8%, and preserved quality of life (ECOG 0) in 82.0%.

Surgeries and complications

As shown in Table 2, surgery was performed in relation to invasive cancer in 82.9% of the cases, while the rest were due to benign causes or complications associated with the endoscopic procedure. The resected lesion was located in the rectum in 30.3% of the patients, and 15.8% (172) of the patients required pre-operative neoadjuvant treatment. Overall, the laparoscopy was the most commonly used approach, in up to 69.7% of the patients. The most common types of surgery were sigmoidectomy (28.7%), right hemicolectomy (24.9%) and low anterior resection (23.1%). The median admission time was seven days (interquartile range 6–10). Post-surgical in-hospital complications were detected in 19.2% of the surgical patients. They were mild (I-II) in 13.4% of the patients and serious (III-V) in 5.9%, with two deaths (0.2%).

After a median follow-up of 25 months (interquartile range 17–34), postoperative complications were detected in 159 patients (14.6%), predominantly related to occlusive or subocclusive conditions (n = 32; 3.0%), hernias or eventration (n = 31; 2.9%) and intra-abdominal collections (n = 23; 2.1%). Forty-one (41) patients died during follow-up (3.8%).

Table 1 Baseline characteristics of operated patients participating in colon cancer screening.

	Frequency	Percentage (%)
Sex (n = 1,092)		
Female	368	33.7
Male	724	66.3
Age (n = 1,092)		
<60 years	306	28.0
≥60 years	786	72.0
Faecal haemoglobin (n = 1,012)		
<100 μg Hb/g	306	30.2
100–199 μg Hb/g	277	27.4
≥200 μg/g	429	42.4
ASA (n = 1,005)		
I	611	60.8
II	343	34.1
III	51	5.1
ECOG (n = 1,005)		
0	824	82.0
1	181	18.0
Colonoscopies performed (n = 969)		
0	122	12.6
1	807	83.3
>1	40	4.1
Tertiary hospital (n = 1,092)		
No	714	65.4
Yes	378	34.6
Health area (n = 1,092)		
Ferrol	236	21.6
Ourense	232	21.2
Pontevedra	113	10.3
Lugo	133	12.2
Santiago	175	16.0
Vigo	95	8.7
Coruña	108	9.9

ASA, American Society of Anesthesiologists; ECOG, Eastern Cooperative Oncology Group.

Factors associated with the appearance of complications

Table 3 shows the variables in the univariate analysis associated with the appearance of in-hospital and post-discharge complications, both overall and serious. In this analysis, in-hospital complications were statistically significantly associated with the type of surgery and the type of hospital. Serious complications were statistically associated with the type of approach, the hospital and the performance status. Finally, post-discharge complications were associated with age, surgical approach and the appearance of in-hospital complications.

In the multivariate analysis, male sex was independently associated with in-hospital complications, both overall (OR: 2.0; 95% CI: 1.3–3.0) and serious (OR: 2.6, 95% CI: 1.2–5.5). Surgery at a tertiary hospital (OR: 0.5; 95% CI: 0.2–0.9) and ECOG 1 (OR: 0.2; 95% CI: 0.05–0.6) reduced the risk of

Table 2 Description of the lesion, surgical procedure and associated complications in the study patients.

	n (%)
Type of lesion (n = 1,092)	
Benign	180 (16.5%)
Complications	5 (0.5%)
CRC pT1	199 (18.2%)
Other CRCs	705 (64.6%)
Other	3 (0.3%)
Surgical approach	
Transanal	62 (5.7%)
Laparoscopy	689 (63.1%)
Converted laparoscopy	73 (6.7%)
Open surgery	264 (24.3%)
Type of surgery	
Abdominoperineal amputation	19 (1.7%)
Extended appendectomy	10 (0.9%)
Segmental colectomy	2 (0.2%)
Subtotal colectomy	34 (3.1%)
Right hemicolectomy	272 (24.9%)
Left hemicolectomy	82 (7.5%)
Low anterior resection	252 (23.1%)
Segmental resection	37 (3.4%)
Transanal resection	60 (5.5%)
Sigmoidectomy	313 (28.7%)
Other	10 (0.9%)
Classification of complications (Clavien–Dindo)	
0	881 (80.8%)
I	89 (8.2%)
II	57 (5.2%)
III	34 (3.1%)
IV	28 (2.6%)
V	2 (0.2%)
Complications at discharge	
Yes	159 (14.6%)
No	930 (85.2%)
Lost	3 (0.3%)
Type of complications at discharge	
Occlusive/subocclusive symptoms	32 (3.0%)
Anastomotic stricture	11 (1.0%)
Hernia/eventration	31 (2.9%)
Surgical wound infection	8 (0.7%)
Haematoma/seroma	9 (0.8%)
Ostomy complications	7 (0.6%)
Intra-abdominal collections	23 (2.1%)
Secondary symptoms	15 (1.4%)
Systemic complications	8 (0.7%)
Rectal bleeding	6 (0.6%)
Final status	
Alive	1,051 (96.2%)
Dead	41 (3.8%)

CRC, colorectal cancer.

Table 3 Variables associated with complications in the univariate analysis.

Evaluated variables	Complications (n = 210)	p[a]	Serious complications (n = 64)	p[a]	Complications after discharge (n = 159)	p[a]
Sex		<0.001		0.04		0.2
Female	48 (13.1%)		14 (3.8%)		48 (13.0%)	
Male	162 (22.4%)		50 (6.9%)		111 (15.4%)	
Age		0.5		0.7		0.04
<60 years	55 (18%)		19 (6.2%)		34 (11.1%)	
>60 years	155 (19.7%)		45 (5.7%)		125 (16.0%)	
FOB		0.1		0.5		0.06
<100 μg Hb/g	67 (21.9%)		18 (5.9%)		38 (12.5%)	
100–199 μg Hb/g	50 (18.1%)		17 (6.1%)		51 (18.5%)	
≥200 μg Hb/g	70 (16.4%)		19 (4.4%)		56 (13.1%)	
ASA		0.1		0.2		0.4
ASA I	99 (16.2%)		33 (5.4%)		93 (15.2%)	
ASA II	71 (20.7%)		15 (4.4%)		45 (13.2%)	
ASA III	11 (21.6%)		5 (9.8%)		5 (10.0%)	
ECOG		0.7		0.04		0.3
0	147 (17.9%)		49 (6.0%)		121 (14.7%)	
1	34 (18.8%)		4 (2.2%)		22 (12.2%)	
Tertiary hospital		0.004		0.01		0.1
No	155 (21.7%)		51 (7.2%)		112 (15.7%)	
Yes	55 (14.6%)		13 (3.4%)		47 (12.5%)	
Lesion location		0.09		0.06		0.02
Rectum	74 (22.4%)		28 (7.9%)		63 (19.0%)	
Rest of colon	136 (17.9%)		38 (5.0%)		96 (12.6%)	
Neoadjuvant		0.4		0.05		0.1
No	173 (18.8%)		48 (5.2%)		128 (14.0%)	
Yes	37 (21.5%)		16 (9.3%)		31 (18.0%)	
Approach		0.002		0.006		<0.001
Open surgery	68 (25.8%)		25 (9.5%)		60 (23.0%)	
Laparoscopic surgery	109 (15.9%)		31 (4.5%)		77 (11.2%)	
Converted laparoscopic surgery	23 (31.5%)		7 (9.6%)		13 (17.8%)	
Transanal	10 (16.4%)		1 (1.6%)		7 (11.5%)	
Hospital complications						<0.001
No					109 (12.4%)	
Yes					50 (24.2%)	

ASA, American Society of Anesthesiologists; ECOG, Eastern Cooperative Oncology Group; FOB: faecal occult blood.
[a] Differences were analysed using the chi-square test. Differences with p values <0.05 were considered statistically significant.

serious complications. Regarding the factors associated with post-discharge complications, both age over 60 years (OR: 1.5; 95% CI: 1.0–2.3) and rectal location of the lesion (OR: 1.6; 95% CI: 1.1–2.3), as well as the presence of in-hospital complications (OR: 2.2; 95% CI: 1.5–3.2), were independently associated with an increased risk, as can be seen in Table 4.

Discussion

We have described the rates of complications, both in-hospital and at discharge, after colorectal surgeries performed within a CRC population screening programme, as well as the factors associated with them. These rates are low and are within what is expected in cohorts of young patients with little comorbidity. The information we provide is relevant to determine the risks associated with participation in a CRC population screening programme. Moreover, these data are key in making decisions about the treatment of neoplastic colorectal conditions that are candidates for endoscopic treatment: pT1 CRC and advanced benign lesions.

Population-based CRC screening targets a predominantly asymptomatic and previously healthy population and should therefore only be performed after a careful consideration of the possible harm and benefits. In fact, we must emphasise that the vast majority of the patients in our study were ECOG 0 and 1, with only 51 ASA III patients. The harmful effects of CRC screening include colonoscopy complications, possible overdiagnosis, psychological impact and treatment-associated complications. Information about the possible secondary consequences of participating in a CRC screening programme, especially those derived from post-surgical complications, is essential in deciding whether

Table 4 Variables associated with the appearance of complications in the multivariate analysis.

Evaluated variables	Complications during admission (n = 210) OR (95% CI)[a]	Serious complications during admission (n = 64) OR (95% CI)[a]	Complications at discharge (n = 159) OR (95% CI)[a]
Sex			
Female	1	1	1
Male	2.0 (1.3–3.0)	2.6 (1.2–5.5)	1.2 (0.8–1.8)
Age			
<60 years	1	1	1
>60 years	1.0 (0.7–1.4)	0.8 (0.4–1.6)	1.6 (1.0–2.5)
FOB			
<100 μg Hb/g	1	1	1
100–199 μg Hb/g	0.7 (0.4–1.0)	1.0 (0.5–2.0)	1.6 (1.0–2.7)
≥200 μg Hb/g	0.6 (0.4–1.0)	0.7 (0.3–1.4)	1.1 (0.7–1.8)
ASA			
ASA I	1	1	1
ASA II	1.3 (0.9–1.9)	1.0 (0.5–1.9)	0.8 (0.5–1.2)
ASA III	1.4 (0.6–3.2)	5.7 (1.6–20.1)	0.7 (0.2–1.9)
ECOG			
0	1	1	1
1	0.8 (0.5–1.3)	0.2 (0.05–0.6)	0.8 (0.5–1.5)
Tertiary hospital			
No	1	1	1
Yes	0.7 (0.5–1.0)	0.5 (0.2–0.9)	0.9 (0.6–1.3)
Approach			
Transanal	1	1	1
Laparoscopic surgery	0.9 (0.4–1.9)	0.9 (0.4–1.8)	0.9 (0.4–2.0)
Converted laparoscopic surgery	2.0 (0.8–4.9)	2.0 (0.8–4.9)	1.7 (0.6–4.7)
Open surgery	1.6 (0.8–3.5)	1.6 (0.8–3.5)	1.6 (0.7–3.9)
Complications during admission			
No			1
Yes			2.4 (1.6–3.6)

ASA, American Society of Anesthesiologists; ECOG, Eastern Cooperative Oncology Group; CI, confidence interval; OR, odds ratio; FOB, faecal occult blood.

[a] *Odds ratio* and 95% confidence interval calculated using multivariate logistic regression.

to participate.[5] In this sense, there is abundant information available on the risks associated with colonoscopy, although information about overdiagnosis[13] or surgery-related complications is very limited.[5]

In a systematic review analysing the risks associated with CRC screening, eight studies on post-surgical morbidity and mortality were identified. In-hospital complication rates ranged from 14% to 24%, and major complications from 0% to 14%. Reported mortality rates were low, ranging from 0% to 3.3%. The largest study (n = 68,306) reported a 5% reoperation rate and no 30-day mortality.[14] Our results are comparable with published findings. Additionally, our study provides information about long-term complications after colorectal surgery in the context of a population screening programme. This rate, 14.6%, is clearly lower than those documented after colorectal surgeries outside population screening programmes. Similarly, the risks associated with colorectal surgery in screening programmes are lower than those described in the general population due to the characteristics of the population participating in CRC screening programmes. In a prospective study carried out in our setting, post-surgical complications in the general population were detected in up to 40% of patients during admission, in 15% in the month after discharge, and 25% in the first year after surgery.[15] These differences with the data documented in our study are related to various factors associated with the risk of complications: age, comorbidity, quality of life and surgical approach.[16–18] We must bear in mind that the patients in our study are a population group with little comorbidity and a good baseline situation, which explains why the percentage of postoperative complications is lower. Our study attributed statistical significance to the male sex, since this is an independent risk factor for post-surgical complications of colic anastomoses described in the literature. Open, more invasive surgeries are also known to be more associated with a higher incidence of

postoperative complications. Another interesting finding from our study was that undergoing surgery in a tertiary hospital was a protective factor in the development of complications, both intraoperatively and in postoperative care, perhaps accounted for by the team's greater experience or the greater availability of resources (technical and human). In any case, new studies would be needed to elucidate this factor further.

The data provided are especially important in situations in which endoscopic treatment can be an alternative to surgery. In decision-making, not only immediate complications must be assessed, but also those that can limit the patient's quality of life in the long term.[19] This is particularly important in patients with complex benign lesions, which account for 16.5% of surgeries. To reduce the risk of complications, it would be advisable to have reference centres to centralise complex endoscopic resections. Moreover, minimally-invasive approaches should be promoted if surgical treatment is eventually required.[20] Another situation in which this information is relevant is in early-stage CRC (pT1), especially in invasive adenocarcinomas on endoscopically-resected adenomas. In decision-making with the patient, the risk of residual disease after endoscopic resection must be weighed up not only against the risk of in-hospital mortality but also against in-hospital and long-term complications.[11]

Our study has several limitations, mainly related to data collection. Our analysis is retrospective. We obtained the data collected in the screening programme information system, although we were unable to calculate other comorbidity indices or the treatments the patient was undergoing at the time of diagnosis. Neither were we able to collect information associated with the risk of the procedure, such as nutrition or preoperative anaemia, or logically the surgeon's experience. On the other hand, we were able to assess the complications in a multicentre context, since we analysed the complications in all the Galician centres participating in the population screening programme.

To conclude, we have described the indications for surgery, the approach, the type of surgery, and above all both in-hospital and long-term complications in a population-based CRC screening programme in our setting. This information is relevant in estimating the risks associated with the screening programme and in decision-making in situations in which endoscopic treatment is an alternative to surgery.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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