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ARTICLE

Bariatric Surgery

Colorectal cancer after bariatric surgery (Cric-Abs 2020): Sicob (*Italian society of obesity surgery*) endorsed national survey

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BACKGROUND: The published colorectal cancer (CRC) outcomes after bariatric surgery (BS) are conflicting, with some anecdotal studies reporting increased risks. The present nationwide survey CRIC-ABS 2020 (Colo-Rectal Cancer Incidence-After Bariatric Surgery-2020), endorsed by the Italian Society of Obesity Surgery (SICOB), aims to report its incidence in Italy after BS, comparing the two commonest laparoscopic procedures—Sleeve Gastrectomy (SG) and Roux-en-Y gastric bypass (GBP).
METHODS: Two online questionnaires—first having 11 questions on SG/GBP frequency with a follow-up of 5–10 years, and the second containing 15 questions on CRC incidence and management, were administered to 53 referral bariatric, high volume centers. A standardized incidence ratio (SIR—a ratio of the observed number of cases to the expected number) with 95% confidence intervals (CI) was calculated along with CRC incidence risk computation for baseline characteristics.
RESULTS: Data for 20,571 patients from 34 (63%) centers between 2010 and 2015 were collected, of which 14,431 had SG (70%) and 6140 GBP (30%). 22 patients (0.10%, mean age = 53 ± 12 years, 13 males), SG: 12 and GBP: 10, developed CRC after 4.3 ± 2.3 years. Overall incidence was higher among males for both groups (SG: 0.15% vs 0.05%; GBP: 0.35% vs 0.09%) and the GBP cohort having slightly older patients. The right colon was most affected ($n = 13$) and SIR categorized/sex had fewer values < 1, except for GBP males (SIR = 1.07).
CONCLUSION: Low CRC incidence after BS at 10 years (0.10%), and no difference between procedures was seen, suggesting that BS does not trigger the neoplasm development.

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INTRODUCTION

Obesity, defined as Body Mass Index (BMI) of >30 kg/m^2, has become a global epidemic and a growing concern for public health, particularly in industrialized countries. The worldwide prevalence of obesity nearly tripled between 1975 and 2016, affecting ~650 million adults by 2016 [1]. Estimates suggest that the incidence of morbid obesity, defined as obesity complicated by direct related comorbidities, may become 11% of the world's population by 2030 [2]. Likewise, the prevalence of obesity in Italy increased by more than twice the rate in the past 30 years, currently affecting ~6 million adults [3]. This increased prevalence has led to shortened life expectancy and heightened the risk for several diseases [4]. Among these, cancer is indeed the most formidable, with a well-established association between obesity and the risk of developing cancer [5]. The International Agency for Research on Cancer (IARC) has designated 14 types of cancer to be obesity-related [6], and identified factors related to obesity per se, such as chronic low-grade systemic inflammation, insulin resistance, hyperinsulinemia, increased circulating insulin-like growth factor 1 along with the changes in gut microbiota presumed to cause cancerous changes [7]. Colorectal cancer (CRC) is one of the foremost obesity-related cancers. Data for the Italian population has documented that morbidly obese patients ($n = 1333$), the leading candidates for bariatric surgery (BS), happened to be at a higher risk of developing cancer and a higher prevalence of hormone-related tumors (breast 20.9%, followed closely by thyroid cancers) was seen with predominance in females (88.3%) [8].

Bariatric Surgery (BS) is the most effective treatment of morbid obesity so far, offering sustainable long-term weight loss and remission/improvement in obesity-related comorbidities [9]. Consequently, the probability of developing cancer is also expected to reduce. However, the existing data for cancer outcomes after BS alludes to a complicated picture because of conflicting results, particularly for CRC with some anecdotal records of increased risks [10–12], while other studies documenting a reduction in risk for CRC [13–15]. And so, the Italian Society of Obesity Surgery (SICOB), endorsed a nationwide survey, CRIC-ABS 2020 (Colo-Rectal Cancer Incidence After Bariatric Surgery-2020), to report the incidence of CRC in Italy after BS, comparing the two most

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common laparoscopic procedures worldwide—Sleeve Gastrectomy (SG) and Roux-en-Y gastric bypass (GBP) [16].

SUBJECTS AND METHODS

The CRIC-ABS 2020, conducted from May to September 2020, was promoted by The Bariatric Center of Excellence, University of Rome 'La Sapienza' and approved by the Italian Society of BS. The survey was organized through responses to two different online questionnaires: the first comprised of 11 questions addressing the number of GBP and laparoscopic SG surgeries performed between 2010 and 2015, with a minimum follow-up of 5 years and maximum of 10 years, besides the anthropometric data, comorbidities, and CRC cases. The second questionnaire contained 15 questions directed exclusively to the centers reporting CRC cases to collect information on diagnosis, neoplasm location and classification (TNM), and treatment and survival rates (Supplementary files 1 and 2).

The survey was emailed by Softitalia Consulting (Softitalia consulting srl, R. Morghen street, 36 Napoli-Italy) (official society secretariat) and addressed to 53 high volume (>150 procedures/year) referral SICOB centers. If the first contact and request were unanswered, reminders via email, telephone calls, and personal contacts were initiated every 15 days. The included centers are officially contributing to the Italian National bariatric registry, adding all their cases every year, with a minimum compulsory follow-up of 51% update (SICOB's criteria of Bariatric Centre of Excellence). In order to reduce the possibility that inadequate follow-up could affect the reported CRC incidence, a specific patient's phone or office recall was required by every center and only the patients with complete follow-up (100% of the sample) were included into the final population and analyzed. CRC cases were tracked during standard scheduled controls (1, 3, 9 12 postoperative months for the first year and then every 12 months) or at time of re-call.

Table 1. Study population characteristics.

	SG	GBP
Number of operations (N)	14.431	6.140
Mean age ± SD (years)	42.50 ± 12	43.6 ± 13
Male (N) (%)	4.440 (30.77%)	1.704 (27.75%)
Female (N) (%)	9.991 (69.23%)	4.436 (72.24%)
Mean BMI (kg/m^2)	44.21 ± 4	44.63 ± 6

SG sleeve gastrectomy, *GBP* gastric bypass.

Statistical analysis

Descriptive statistics were used to examine anthropometric and clinical characteristics and are expressed as percent (%) and mean ± standard deviation (SD). The overall incidence of CRC in the BS cohort was calculated, followed by a separate subgroup analysis to compare the CRC incidence separately in each cohort—SG and GBP. The incidence of CRC in BS cases was matched to the general population within a similar observation period (5–10 years). In addition, a standardized incidence ratio (SIR) with a 95% confidence interval (CI) was calculated as the ratio of the observed number of cases of CRC to the expected number. If the observed number of cancer cases was equal to the expected number, the SIR is 1; if more cases are observed than expected, SIR is >1 and vice versa. Expected cases were calculated according to the last national report [17]. Also, a cox analysis was performed to establish the impact of comorbidities and final weight corresponding to CRC development. Statistical significance was defined at p value < 0.05. All analyses were conducted using Statistical Software version 8.0 (StatSoft, Tulsa OK).

RESULTS

The CRIC-ABS 2020 survey was administered across 53 SICOB centers, while data were collected from 34 centers (63% responders). Twelve of these centers were located in northern Italy, ten in central, nine in the south, and three in the Islands. The total number of bariatric procedures (GBP and SG, all laparoscopic), performed between 2010 and 2015 and post-operatively checked was 20,571, a majority of them ($n = 14{,}431$, 70%) were SG and while only 30% ($n = 6.140$) were GBP. No differences were registered into the study population in terms of follow-up duration, equally distributed between 5 and 10 years. The subjects in both groups were predominantly females (70.13%), and the mean BMI and age were comparable for both groups, SG and GBP, i.e SG group: mean BMI = 44.21 ± 4 kg/m^2; mean age = 42.50 ± 12 years; GBP group: mean BMI = 44.63 ± 6 kg/m^2; mean age = 43.6 ± 13 years. Table 1 presents the details of anthropometric measures for both groups. No baseline differences between the two analyzed groups were observed.

A total of 22 individuals (incidence rates 0.10%, mean age 53 ± 12 years, 13 males and 9 females) developed CRC during the follow-up, after an average of 4.3 ± 2.3 years. Out of these 22, 12 (0.08%) underwent SG, while the other 10 (0.16%) had a GBP ($p > 0.05$), and these findings were diagnosed after a mean 4.6 ± 1.61 years and 4.7 ± 2.75 years, respectively, from the procedures. Figure 1 illustrates the incidence timeline of CRC occurrence. When the analysis was stratified, the overall incidence was higher among men than women for both groups (SG: 0.158% vs 0.05%;

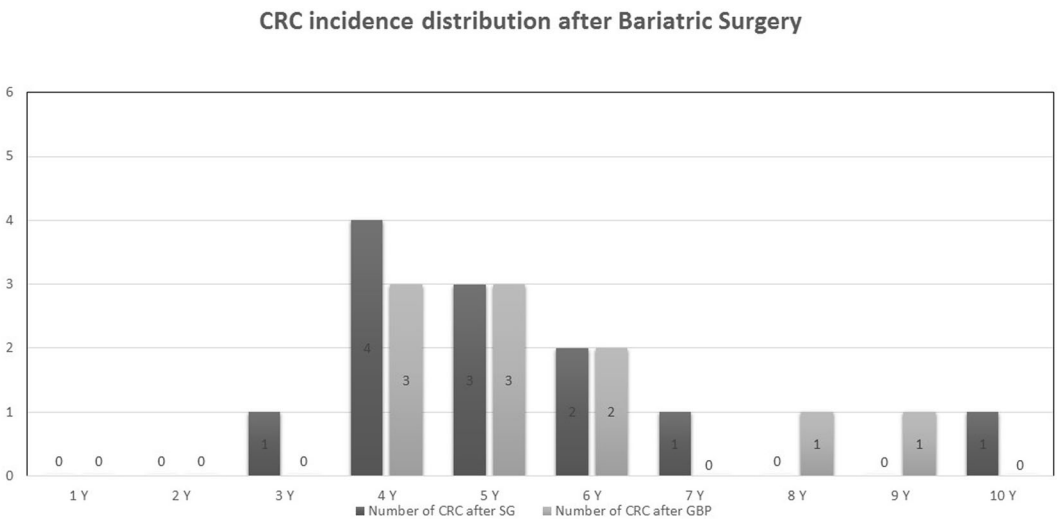

Fig. 1 CRC incidence (number of cases) from 1 to 10 years after bariatric procedure. No statistically significant difference was registered for any period ($p < 0.05$).

Table 2. Characteristics of the patients developing colorectal cancer ($n = 22$) after BS.

	SG	GBP	*P* value
Male (N)	7 (58%)	6 (60%)	n.s.
Incidence (%)	0.158%	0.35%	
Female (N)	5 (42%)	4 (40%)	n.s.
Incidence (%)	0.05%	0.09%	
Mean diagnosis age (Years)	54.75 ± 3.9	56.2 ± 4.2	n.s.
Mean diagnosis BMI ± SD (Kg/m^2)	29.9 ± 3.91	28.5 ± 2.1	n.s.
CRC localization (N)	6 right colon	7 right colon	
	2 transverse colon	1 transverse colon	
	2 left colon	1 left colon	
	2 rectum	1 rectum	

SG Sleeve Gastrectomy, *GBP* gastric bypass.

Table 3. Standardized incidence ratio (SIR) with 95% confidence interval (CI) in bariatric population.

	SG/SIR	GBP/SIR
Male (N)	7/0.5 [CI = 0.2–0.72]	6/1.07 [CI = 0.91–1.2]
Female (N)	5/0.6 [CI = 0.3–0.76]	4/0.8 [CI = 0.32–0.94]

GBP: 0.35% vs 0.09%), and the GBP cohort was slightly older at the time of CRC diagnosis (56.2 ± 4 years vs 54.75 ± 3.9 years). The mean postoperative BMI in the SG group was 29.9 ± 3.91 kg/m^2 as compared to 28.5 ± 2.1 kg/m^2 in the GBP group.

Regarding anatomical site-specificity of the neoplasm, the most affected was the right side of the colon in both groups ($n = 13$), with seven cases in the SG group and the rest six in the GBP group (Table 2). The first event depicting clinical onset on tumor manifestation was anemia in most cases, i.e., 84% after SG, and 70% after GBP. Major comorbidities at the time of CRC diagnosis were type II diabetes (T2DM)—13%, obstructive sleep apnea syndrome (OSAS)—23%, and hypertension (HTA)—16%. And, according to the TNM staging of disease at the time of diagnosis, no patients had stage IV cancer in either group, while three patients with stage I, five with stage II, four with stage III were there in the SG group, compared to four patients with stage I, three patients each of stage II and III in the GBP group ($p = 0.9\%$). The survival rates in both groups were comparable, 83.3% in the SG group vs 80% in the GBP group, with no significant differences in overall survival rates till date ($p = 0.4\%$).

CRC cases were observed in 12 of the 34 centers, out of which six were in north Italy, three in central, two in southern, and one in the Islands. The cox analysis did not reveal a statistically significant association between major comorbidities (T2DM, HTA, OSAS), final weight/BMI, and CRC diagnosis. The SIR (observed number of CRC cases divided by the 'expected' number of cases) classified for gender sex showed fewer cases with a value <1 (range = 0.5–0.8), except for males after GBP (SIR = 1.07). The class interval was calculated around the last SIR to estimate the effect of a random result demonstrating a value into 1 (SIR = 1.07; 95% CI = 0.91–1.2), confirming that the SIR was not statistically significantly elevated. The population SIR is reported in Table 3.

DISCUSSION

This survey-based research by the SICOB aimed to delve deeper into the controversial association between the risk of developing obesity-related CRC and established treatment for morbid obesity, bariatric surgeries. Swedish cohort studies by Derogar et al. and Ostlund et al. highlighted an increased SIR for CRC in the long-term in patients undergoing BS compared to the non-operated group, whereas the SIR continued to be stable at 10 years follow-up [10, 11]. Derogar et al. [10]. described an increased SIR (SIR = 2.00; 95% CI = 1.48–2.64) in 15,095 BS patients compared to 62,016 non-BS patients. In addition, for both the groups, SIR was higher in males (SIR = 2.17) than females (SIR = 1.40) without significant differences between the bariatric procedures analyzed (vertical banded gastroplasty, adjustable gastric banding, and GBP). Similarly, Ostlund et al. [11] recorded that SIR doubled in BS patients (SIR = 2.14), with a higher incidence in male patients. Both the authors concluded that BS meant for weight-loss did not protect the patients against CRC development, rather, they suggested a time-dependent increase in CRC risk after BS. Another analysis by Mackenzie et al. in 2018 [12] made a striking revelation that more-than-twice increased risk of CRC following BS, particularly GBP, compared with those who did not undergo any BS, which was in direct contrast to hormone-related cancers (breast, endometrial, and prostate) for which the risk decreased in the same BS group. Likewise, Tao et al. [18] in a large cohort from five Nordic countries, found an increased risk of colon cancer after BS, with the BS group having a greater SIR (SIR = 1.56; 95% CI = 1.28–1.88) compared to the general population and the hazard ratio (HR) of the neoplasm incidence became significant (1.55; 95% CI = 1.04–2.31) 10–14 years after BS vs surgical and nonsurgical cohorts [18]. Conversely, our national survey based on a large BS cohort of 20,575 patients reported a very low overall incidence of 0.10% at a maximum of 10 years after BS.

When analyzing the bariatric procedures exclusively, we found no statistically significant difference in CRC incidence between the two matched procedures ($p = 0.7$), i.e., 0.08% after SG and 0.16% after GBP. This is in contrast to the hypothesis presented in previous studies [10, 12, 19–22] that the risk of CRC is more with GBP than SG. However, the preponderance of a higher CRC incidence in males observed in our study was similar to Arnold et al. [23] and IARC studies [6], demonstrating a slightly greater incidence in the male gender—0.35% after GBP and 0.16% after SG in males vs 0.05% after GBP and 0.09% after SG in females. These results are consistent with data observed for the general Italian population [24, 25] and reflect the results of a large literature experience recently published.

The retrospective cohort study by Bailly et al. [13] on 1,045,348 subjects suggested that patients share the same risk of developing CRC following BS ($n = 74$, 131) as the general population and 32% lower than nonsurgical patients. Similarly, Aravani et al., in a UK based study found no change in CRC risk over time in those undergoing BS compared with the general population [26]. Moreover, the systematic review and meta-analysis by Afshar suggested that BS decreases the risk of CRC significantly compared to non-operated obese patients (27% less, $p = 0.004$) [15]. Similar to previous studies, Schauer et al. [12] and Kwak et al. [27] observed a protective effect of the BS on CRC risk. The recent systematic review and meta-analysis by Wiggins et al. (2018) also support these findings [28]. The SIR obtained in our study was <1, reaffirming that BS per se does not predispose the patient to a higher risk of developing CRC.

The higher value of 1.07 in male patients after GBP after the sub-analysis on CIs was related to a random effect without statistical significance. Interestingly, the mean CRC diagnosis time after SG and GBP, 4.6 ± 1.61 years and 4.7 ± 2.75 years respectively, together with the mean incidence age, 56.2 ± 4 years vs 54.75 ± 3.9 years respectively, wasn't statistically significant ($p > 0.05$) and mirrors the mean incidence age for the general Italian population (range 50–69 years) [25]. No specific risk factors, such as comorbidities and weight, were highlighted from the sub-analysis, probably due to the low cumulative incidence. The incidence

timing (median 4–6 years post operatively) was independent from the follow-up timing and needs, in the future, specific evaluation addressing the reason of this distribution From the TNM stage analysis of CRC diagnosis between the 22 patients, seven were stage I, eight from stage II, seven from stage III, and none at stage IV, with anemia as a key symptom in more than 80% of these patients (83.3% after SG, 90% after GBP). This data may be explained by the strict follow-up which bariatric patients are subjected to, biannual or annual clinical evaluations, blood test analysis, radiological, and endoscopic examinations. A prompt diagnosis guaranteed an effective treatment, with an overall survival rate of 80% after a minimum follow-up of 5 years (4 deaths on 22 patients in the latest follow-up at 10 years).

All these data must be interpreted based on the study limitations: sample size not including the total bariatric Italian population (drop-out of 37% of the bariatric centers during the enrolment phase), eventual CRC diagnosis made in patients lost to bariatric follow-up, the prevalence in females (71.3 vs 28.7%), absence of specific CRC familiar anamnesis, the absence of no-bariatric obese control group (due to no specific national data available) and the small number of events (22 on 20,571) that do not guarantee a powerful evidence particularly in terms of SG-GBP comparison.

However, the strengths of the study are represented by its originality, the inclusion of the National Italian Report on CRC incidence after BS, exclusive participation of recognized national bariatric referral centers with a standard approach to patient screening and follow-up, strict statistical analysis, large population, and long-term follow-up (5–10 years).

CONCLUSION

The present study represents the first national survey endorsed by SICOB (Italian Society of Obesity Surgery) on CRC incidence after laparoscopic SG and GBP surgeries reporting the primary data in this field. The results reported a low incidence of CRC at 10 years follow-up (0.10%) without a statistically significant difference between the two procedures (GBP vs SG), suggesting that BS does not trigger neoplasm development even at 10 years. However, further studies conducted on a larger scale may help support these findings.

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AUTHOR CONTRIBUTIONS

MCC and AI Designed and wrote the study protocol. Create the survey form and elaborate the data. CEB and FDA Reviewed the manuscript andhelps to analyze the results. PT and MG Elaborate tha data and merged the database. GS Supervised the outcomes and the data analysis. Coordinate the centers involved. CRIC-ABS group Partecipate actively to the survey and provide access to their database.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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