original reports

Colorectal Cancer Treatment Characteristics and Concordance With Guidelines in Sri Lanka: Results From a **Hospital-Based Cancer Registry**

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PURPOSE Colorectal cancer (CRC) ranks among the top five incident cancers in Sri Lanka (SL). Here, we describe disease characteristics and treatment patterns of patients with CRC in SL.

METHODS All adult patients (age > 18 years) diagnosed with CRC during 2016-2020 were identified from the National Cancer Institute SL cancer registry. Cancer stage at diagnosis was defined according to the seventh edition of the TNM staging system. Concordance between recommendations for adjuvant therapy and actual rates of delivery was also analyzed. Descriptive statistics were used to describe the study cohort and treatment patterns.

RESULTS A total of 1,578 patients were diagnosed with CRC during the study period, 53% (n = 830) with colon cancer and 47% (n = 748) with rectal cancer. Mean age was 61 (range, 18-91) years. Stage distribution was 13%, 28%, 46%, and 12% for stage I, II, III, and IV cancers, respectively. Adjuvant chemotherapy was delivered to 82% of patients with stage III colon cancer. There was a lack of concordance with delivery of neoadjuvant chemoradiotherapy, which was only delivered to 50% of patients with stage III rectal cancer for whom this treatment was indicated.

CONCLUSION Aging population and advanced stage of CRC at diagnosis will continue to challenge the provision of high-quality CRC care in SL. Further quantitative and qualitative research may help better understand the nonconcordance with treatment guidelines. Such information would help ease the burden of advanced-stage CRC in SL.

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INTRODUCTION

Colorectal cancer (CRC) is currently among the top five highest incidence cancers in Sri Lanka (SL), with a age-standardized rate of 10.2 per 100,000 population in 2019.1 Increasing incidence of CRC has been previously described in SL and noted to have changed from a WHO age-standardized rate of 2.9/100,000 in 2001 to 6.08/100,000 in 2010.2 This study, however, was limited by lack of information on staging, pathology, or treatment, and had very sparse demographic information.

The Sri Lankan cancer system provides universal free cancer care, accessible regional cancer treatment units, and a national oncology training program. During the period of study, cancer care was delivered through 19 regional cancer treatment centers covering all nine provinces.3 The National Cancer Institute SL (NCISL) is SL's only dedicated cancer hospital, and provides treatment to approximately 40% of all patients with cancer in SL (approximately 12,000 cases in 2020).¹ Patients with CRC are often referred to NCISL following surgery for adjuvant therapy or for neoadjuvant/ palliative treatment. Although cancer care pathways have expanded in the past few decades,³ the system continues to face challenges, including inadequate radiation therapy facilities and an exodus of SL-trained oncologists to high-income countries.^{3,4}

CRC screening programs in developing countries such as SL are rare, and this has likely led to a higher proportion of advanced-stage CRC at diagnosis.⁵ The relationship between sociodemographic factors and CRC stage at diagnosis has not been explored in SL, and there are limited data from other low-middle income countries (LMICs).6 There is also very limited information on treatment patterns for CRC in SL and

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CONTEXT

Key Objective

This study was conducted with the objective of addressing the issue of paucity of information on patient population and treatment patterns for colorectal cancer (CRC) in Sri Lanka (SL), despite it being one of the top five incident cancers in the country.

Knowledge Generated

Nearly 60% of CRCs in SL were of advanced stage at diagnosis. Furthermore, this study found a lack of concordance with treatment guidelines, including both underuse (eg, neoadjuvant chemoradiotherapy only delivered to 50% of patients with stage 3 rectal cancer) and overuse (eg, chemotherapy delivered to 38% patients with stage 1 colonic cancer) of clinical treatments.

Relevance

This article provides impetus for further investigation into CRC treatment and guideline concordance in SL and other low- and middle-income nations, where limited research like this have been conducted.

their congruence to guidelines. Although neoadjuvant treatment is recommended for stage III rectal cancers and adjuvant treatment for stage III colon cancers, we have very limited information on the practice patterns of SL and its concordance to guidelines.⁷

In this study, we aim to describe the disease characteristics and treatment patterns in a large cohort of patients with CRC and evaluate the concordance between prescribed treatments and national guidelines. Follow-up and treatment outcomes have not been described in this iteration of results as we continue to collect a longer duration of follow-up information prospectively in this cohort, to facilitate meaningful interpretation of these outcomes.

METHODS

Study Population

Study participants included adult patients (age > 18 years) with newly diagnosed CRCs from January 1, 2016, to December 31, 2020, identified from the NCISL cancer registry. The NCISL CRC registry is a prospectively maintained database that includes all CRCs treated at the NCISL since the registry's inception in 2016. The data were collected at the time of initial presentation to NCISL and in follow-up every 6 months. Trained data collectors conducted one-on-one in person or telephone-based interviews with patients with or without their caregivers after informed consent was obtained. Clinical information was corroborated through their clinic records in hospital. Details on database establishment, data capture, and validation have been published elsewhere.8 Comprehensive information on patient characteristics, care pathways, and follow-up were obtained from patients presenting to the NCISL.

Definitions of Exposures and Outcomes

In this study, information was collected on the following sociodemographic characteristics: age, sex, alcohol and smoking history, marital status, self-reported highest education level completed, household income, comorbidities,

and physical measurements (body mass index). Comorbidity was measured using the Charlson Comorbidity Index on the basis of documented comorbidities at diagnosis.9 Staging at diagnosis was defined according to the TNM (eighth edition) staging system. 10 Pathologic TNM staging was used for all patients who had undergone definitive surgery, and clinical TNM staging was used for the rest. In the cases of missing data, registry staff reviewed primary case sheets and followed up by phone to capture sociodemographic and treatment data. The use of neoadjuvant and adjuvant therapies was assessed for both colon and rectal cancers by stage. Concordance was analyzed between guideline recommendations for use of neoadjuvant (chemotherapy ± radiotherapy) or adjuvant therapy for CRC and actual rates of delivery of such therapies. Commonly used guidelines in Sri Lankan oncology clinical practice, which include National Institute for Health and Care Excellence, UK, and National Comprehensive Cancer Network, were used as the standard for comparison. 11,12 This comparison was made on the basis of initiation and documented delivery of therapies using clinical records that include paper-based treatment administration logs maintained at the hospital. These included chemotherapy for stage III CRC and neoadjuvant therapy for stage III rectal cancer.

Statistical Analysis

Categorical measures were summarized as numbers with percentages, and continuous variables were summarized as means with standard deviations.

Ethics Statement

Ethical approval for this study was obtained from the Faculty of Medicine, University of Colombo Ethics Review Committee (Ref. No. EC-17-068). All methods were performed in accordance with the appropriate ethical guidelines and regulations. Informed consent was obtained from all participants.

TABLE 1. Demographic and Tumor Characteristics of Patients With Colorectal Cancer Diagnosed During 2016-2020 at the National Cancer Institute, Sri Lanka

50-59 2 60-69 2 70+ 1 Year of diagnosis 2016 1 2017 1 2018 1 2019 2	57 (63) 97 (51) 201 (51) 299 (52) 76 (52) 31 (55) 17 (50) 96 (54) 202 (52) 84 (52)	33 (37) 92 (49) 190 (49) 272 (48) 161 (48) 106 (45) 116 (50) 170 (46) 184 (48)	90 (6) 189 (12) 391 (25) 571 (36) 337 (21) 237 (15) 233 (15) 366 (23)
40-49 50-59 2 60-69 270+ 1 Year of diagnosis 2016 2017 2018 1 2019 2	97 (51) 201 (51) 299 (52) .76 (52) .31 (55) .17 (50) .96 (54)	92 (49) 190 (49) 272 (48) 161 (48) 106 (45) 116 (50) 170 (46)	189 (12) 391 (25) 571 (36) 337 (21) 237 (15) 233 (15) 366 (23)
50-59 2 60-69 2 70+ 1 Year of diagnosis 2016 1 2017 1 2018 1 2019 2	201 (51) 299 (52) .76 (52) .31 (55) .17 (50) .96 (54) .202 (52)	190 (49) 272 (48) 161 (48) 106 (45) 116 (50) 170 (46)	391 (25) 571 (36) 337 (21) 237 (15) 233 (15) 366 (23)
60-69 22 70+ 1 Year of diagnosis 2016 1 2017 1 2018 1 2019 2	.31 (55) .17 (50) .96 (54) .202 (52)	272 (48) 161 (48) 106 (45) 116 (50) 170 (46)	571 (36) 337 (21) 237 (15) 233 (15) 366 (23)
70+ 1 Year of diagnosis 2016 1 2017 1 2018 1 2019 2	31 (55) 17 (50) 96 (54) 202 (52)	161 (48) 106 (45) 116 (50) 170 (46)	237 (15) 233 (15) 236 (23)
Year of diagnosis 2016 1 2017 1 2018 1 2019 2	31 (55) 17 (50) 96 (54) 202 (52)	106 (45) 116 (50) 170 (46)	237 (15) 233 (15) 366 (23)
2016 1 2017 1 2018 1 2019 2	.17 (50) .96 (54) .202 (52)	116 (50) 170 (46)	233 (15) 366 (23)
2017 1 2018 1 2019 2	.17 (50) .96 (54) .202 (52)	116 (50) 170 (46)	233 (15) 366 (23)
2018 1 2019 2	.96 (54)	170 (46)	366 (23)
2019 2	202 (52)		
		184 (48)	306 (04)
2020 1	.84 (52)	(10)	386 (24)
		172 (48)	356 (23)
Sex			
Male 3	379 (47)	422 (53)	801 (51)
Female 4	51 (58)	326 (42)	777 (49)
Marital status			
Single	44 (54)	37 (46)	81 (5)
Married 7	'42 (53)	661 (47)	1,403 (89)
Widowed	30 (47)	34 (53)	64 (4)
Divorced/separated	4 (44)	5 (56)	9 (1)
Missing	10 (48)	11 (52)	21 (1)
Education level			
None	78 (45)	95 (55)	173 (11)
Primary school 2	252 (55)	203 (45)	455 (29)
Secondary school 1	.26 (57)	94 (43)	220 (14)
> Secondary school	31 (60)	21 (40)	52 (3)
Missing 3	343 (51)	335 (49)	678 (43)
Charlson comorbidity score			
0 5	573 (52)	523 (48)	1,096 (69)
1 2	221 (52)	201 (48)	422 (27)
> 1	36 (60)	24 (40)	60 (4)
T stage ^c			
T0	1 (50)	1 (50)	2 (0)
T1	29 (52)	27 (48)	56 (3)
T2 1	.11 (51)	107 (49)	218 (14)
T3 4	65 (53)	414 (47)	879 (56)
T4 2	24 (53)	199 (47)	423 (27)
N stage ^c			
NO 3	397 (56)	307 (44)	704 (45)
N1 2	272 (51)	259 (49)	531 (34)
N2 1	.54 (46)	179 (54)	333 (21)
N3	7 (78)	2 (22)	9 (0)

TABLE 1. Demographic and Tumor Characteristics of Patients With Colorectal Cancer Diagnosed During 2016-2020 at the National Cancer Institute, Sri Lanka (Continued)

Characteristic	Colon (n = 830) No. (% ^a)	Rectal (n = 748) No. (% ^a)	Total (N = 1,578) No. (%b)
Missing	1 (100)	0 (0)	1 (0)
M stage			
MO	721 (52)	665 (48)	1,386 (88)
M1	109 (57)	83 (43)	192 (12)
Stage category			
0	1 (50)	1 (50)	2 (0)
I	106 (51)	102 (49)	208 (14)
II	265 (59)	181 (41)	446 (28)
III	349 (48)	381 (52)	730 (46)
IV	109 (57)	83 (43)	192 (12)
Histology type			
Adenocarcinoma	750 (53)	672 (47)	1,422 (90)
Mucinous carcinoma	39 (71)	16 (29)	55 (4)
Other	11 (50)	11 (50)	22 (1)
Missing	30 (38)	49 (62)	79 (5)
Differentiation			
Well	40 (56)	31 (44)	71 (4)
Moderate	689 (54)	594 (46)	1,283 (81)
Poor	26 (56)	20 (44)	46 (3)
Missing	75 (42)	103 (58)	178 (12)
Total	830 (53)	748 (47)	1,578 (100)

^aThe percentages were calculated using the row total as the denominator.

RESULTS

The study population included 1,578 patients with CRC who were treated at the NCISL from January 1, 2016, to December 31, 2020. Characteristics of the study cohort are listed in Table 1. Fifty-three percent (830/1,578) of patients had colon cancer. The mean age was 61 years (range, 18-91 years) with slightly more males than females (51% v 49%). The highest number of colorectal cases (n = 571; 36%) were in individuals age 60-69 years. Most were married (n = 1,403; 89%) and had at least a primary school education (n = 727; 46%), although 43% of values were missing. A total of 482 (30%) patients had comorbidities, indicated by a Charlson comorbidity score of 1 or > 1. Majority of the patients presented with T3 or T4 (n = 1,302/1,578; 82%) and had nodepositive disease (n = 874/1,578; 55%). Similarly majority of tumor stages were stage III (n = 730; 46%), whereas 13%,

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^bThe percentages were calculated using the column total (N = 1,578) as the denominator unless otherwise specified.

^cPathologic TNM staging was used for all patients who had undergone definitive surgery and for the rest, clinical TNM staging was used.

TABLE 2. Surgical Treatment Characteristics of Patients With Colorectal Cancer Diagnosed During 2016-2020 at the National Cancer Institute, Sri Lanka

Type of Treatment	Colon No. (%)	Rectum No. (%)	Total No. (%)
Surgery			
Abdominoperineal resection	0 (0)	122 (16)	135 (9)
AR	184 (22)	335 (45)	467 (30)
Colectomy	462 (56)	0 (0)	499 (32)
Defunctioning stoma only	8 (1)	4 (1)	12 (1)
Hartmann's procedure	35 (4)	13 (2)	48 (3)
No surgery	111 (13)	252 (34)	363 (23)
Other	30 (4)	22 (3)	54 (3)
Total	830 (100)	748 (100)	1,578 (100)

Abbreviation: AR, anterior resection.

28%, and 12% were of stage I, II, and IV, respectively. The staging distribution was comparable between colon and rectal cancers. As expected, majority of the pathology was adenocarcinoma (n=1,422/1,578;90%) for both colon and rectal cancers.

Distribution of surgical treatment of CRC can be found in Table 2. The most common surgery performed was colectomy (n = 499; 32%), followed closely by anterior resection (n = 467; 30%).

Neoadjuvant and adjuvant therapy details are shown in Table 3. Forty-one percent of patients with stage I colonic cancers have received chemotherapy, whereas 64% of patients with rectal cancer have received chemotherapy or radiotherapy. Although it was not possible to segregate stage II into high-risk or low-risk and no data were captured on microsatellite instability status, the percentage of stage II patients who received chemotherapy is substantial at 77% (343/446). For stage III patients, receipt of chemotherapy (neoadjuvant or adjuvant) was 81% (594/730).

Less than half of the patients (48%) with stage II-III rectal cancer received neoadjuvant therapy. Majority of patients (80%) with stage II-III colon cancer who did not receive neoadjuvant therapy were given adjuvant therapy. A smaller number of patients (57%) with stage II-III rectal cancer who did not receive neoadjuvant therapy were given adjuvant therapy. Over 75% of both colon and rectal cancer patients were given either adjuvant or neoadjuvant therapy (n = 1,221).

Concordance between recommendations for the use of adjuvant therapy for CRC and actual rates of delivery of adjuvant therapies for patients is noted in Table 4. The rate of adjuvant chemotherapy delivered for indicated patients was 73% (n = 376). Only 50% of patients with stage III rectal cancer received neoadjuvant therapy before definitive surgery.

DISCUSSION

To our knowledge, this is the largest cohort study published on patients with CRC in SL that describes their pathology, staging, and treatment characteristics.² The majority of our cohort had advanced disease (stage III or IV) at diagnosis. Neoadjuvant therapy was used in only half of patients where it was absolutely indicated (stage III rectal cancer), and adjuvant therapy use was satisfactory with approximately three quarters of indicated patients receiving therapy. Our results also show concerning overtreatment, with 16% of patients with stage I disease receiving chemotherapy.

Overall, our cohort characteristics were largely consistent with previous studies evaluating CRC epidemiology, where the mean age at diagnosis was 58 years versus 61 years in our cohort with similar sex distribution.² However, there is a greater proportion of rectal cancers (53%) compared with national data (43%) included in this study sample.¹³ This result may be the product of a referral bias in which patients with colon cancer are more likely to be treated in regional facilities, whereas rectal cancers are referred to NCISL for

TABLE 3. Neoadjuvant and Adjuvant Treatment of Patients With Colorectal Cancer by Stage at Diagnosis During 2016-2020 at the National Cancer Institute, Sri Lanka

Type of Treatment by Stage ^a at Diagnosis	l n/N (%)	II n/N (%)	III n/N (%)	IV n/N (%)	Total n/N (%)
Colon cancer					
NAT	4/106 (4)	12/265 (5)	30/349 (9)	13/109 (12)	59/829 (7)
Adjuvant/palliative chemotherapy (excluding NAT patients)	39/102 (38)	187/253 (74)	268/319 (84)	83/96 (86)	577/770 (75)
Total chemotherapy	43/106 (41)	199/265 (75)	298/349 (85)	96/109 (88)	636/829 (77)
Rectal cancer					
NAT	31/102 (30)	83/181 (46)	191/381 (50)	19/83 (23)	324/747 (43)
Adjuvant/palliative chemotherapy or RT (excluding NAT patients)	34/71 (48)	61/98 (62)	105/190 (55)	61/64 (95)	261/423 (62)
Total chemotherapy ± RT	65/102 (64)	144/181 (80)	296/381 (78)	80/83 (96)	585/747 (78)

Abbreviations: NAT, neoadjuvant therapy; RT, radiotherapy.

^aClinical TNM stage is used for neoadjuvant therapy and pathologic TNM used for adjuvant therapy.

TABLE 4. Delivery of Adjuvant and Neoadjuvant Treatments and Guideline Concordance for Colorectal Cancer Diagnosed Between 2016 and 2020 at the National Cancer Institute, Sri Lanka

Indicator	Treatment Indicated No. (%)	Treatment Delivered No. (%)
Use of adjuvant chemotherapy (excluding patients who received neoadjuvant therapy)		
Recommendation: adjuvant chemotherapy should be delivered to patients with stage III disease (up to 2019)	514 (100)	376 (73)
Use of NAT		
Recommendation: NAT should be delivered to patients with stage III rectal cancer	381 (100)	191 (50)

Abbreviation: NAT, neoadjuvant therapy.

more complex case management. However, greater investigation is required to confirm this.

Colon cancer was found to be more common in women (58%), whereas rectal cancers were more common in men. Data from the SL National Cancer Registry show a similar trend.¹ However, data from other countries report greater incidence for both colon and rectal cancers among male patients.¹⁴ The reasons for the observed gender difference in SL are unclear and warrant further investigation.

The majority of patients were between age 60 and 69 years, which is consistent with previous studies. SL has the fastest aging population in South Asia. This aging population combined with rising CRC cases will likely increase the CRC burden in SL, highlighting the need for increases and improvements in treatment services.

A large proportion (75%; n = 1,176) of cases in this study were diagnosed with mid-stage (stage II and III) disease at diagnosis. Similar findings were presented in a past Sri Lankan study, which found 60% (n = 409) of patients were diagnosed with mid-stage disease.13 These current and past data point to an enduring and concerning trend regarding screening and diagnosis and indicate the need for enhanced screening at a population level through fecal occult blood testing and colonoscopy in high-risk patients. Despite calls for increased population-based screening for CRC. 5,16 SL, like many other South Asian countries, does not have a population-based CRC screening program. 17 Stage at diagnosis is the most important prognostic factor for determining survival; thus, greater efforts must be made to establish and promote population-based CRC screening programs in SL.

Despite lacking information on patients' performance status and other comorbidities, overall concordance with treatment guidelines was promising for adjuvant therapy. Every three out of four eligible patients with colon cancer and more than half of eligible patients with rectal cancer who did not receive neoadjuvant therapy received adjuvant

therapy. However, the concordance to guidelines was poor for use of neoadjuvant therapy, where less than half of the patients with an absolute indication for neoadjuvant therapy for rectal cancer received treatment. Similar patterns of low use of preoperative chemoradiation for rectal cancer have been reported from many Asian countries including Philippines, Japan, and Korea. 18 Potential explanations for incongruence in adherence to treatment guidelines include a lack of access to radiotherapy, as there were only seven radiotherapy facilities in SL during the study period,3 long wait times for radiotherapy, 19 and upfront surgery performed in smaller hospitals, which lack quick access to oncology consultation. Furthermore, patient comorbidities, emergency presentation, socioeconomic factors, poor health literacy, and surgeon perceptions on use of neoadjuvant therapy may also influence this. However, these factors were not explored in this study, thus suggesting an area for further research.

Equally important, concerning overtreatment rates were found in the study. Despite lack of access being one of the most frequently cited issues in global oncology, several patients with stage I disease who were not indicated for chemotherapy received chemotherapy in our cohort. The reasons for this should be explored further, but this study is an indication that potential overtreatment can occur in LMICs as well. This may be a potential area that requires advocacy for inclusion in Choosing Wisely campaigns in LMICs.

The study has several limitations to note. Some data were incomplete or missing, particularly for demographic characteristics, such as level of education. The data from 2016 and 2017 may also under-represent late-stage CRCs, as some charts of deceased patients were not accessible at the time of data collection. It is estimated that these cases accounted for < 7% (n < 100) of patients in the cohort. Another limitation to this study is the patient population, which only included patients from NCISL. Although NCISL treats patients from across the country, this limits the generalizability of the results. Furthermore, treatments performed at other centers were not included in this study, potentially leading to a greater proportion of rectal cancer cases, and gaps in data related to uptake of treatment. Finally, several elements of the data were not explored in depth, such as reasons for nontreatment. This lack of qualitative data indicates a need for further research on this topic.

In conclusion, the data add significant value to the knowledge base while indicating a need for further research. Our findings highlight the late presentations in an older population of patients and the incongruence to guideline-based therapy. Further quantitative and qualitative research may help better understand the reasoning behind these findings. Such information would be prudent to help ease the burden of advanced-stage CRC in SL and reduce its burden on the health care system.

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DATA SHARING STATEMENT

The data sets analyzed during the current study are not publicly available as the ethics approval for this research does not provide data sharing because the data contain individual patient identification information. However, the data are available from the corresponding author on reasonable request.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

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