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COVID-19

The effect of the first year of the COVID-19 pandemic on sphincter preserving surgery for rectal cancer: A single referral center experience

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ABSTRACT

Background: COVID-19 has significantly impacted healthcare worldwide. Lack of screening and limited access to healthcare has delayed diagnosis and treatment of various malignancies. The purpose of this study was to determine the effect of the first year of the COVID-19 pandemic on sphincter-preserving surgery in patients with rectal cancer.

Methods: This was a single-center retrospective study of patients undergoing surgery for newly diagnosed rectal cancer. Patients operated on during the first year of the COVID-19 pandemic (March 2020–February 2021) comprised the study group (COVID-19 era), while patients operated on prior to the pandemic (March 2016–February 2020) served as the control group (pre–COVID-19).

Results: This study included 234 patients diagnosed with rectal cancer; 180 (77%) patients in the pre–COVID-19 group and 54 patients (23%) in the COVID-19–era group. There were no differences between the groups in terms of mean patient age, sex, or body mass index. The COVID-19–era group presented with a significantly higher rate of locally advanced disease (stage T3/T4 79% vs 58%; $P = .02$) and metastatic disease (9% vs 3%; $P = .05$). The COVID-19–era group also had a much higher percentage of patients treated with total neoadjuvant therapy (52% vs 15%; $P = .001$) and showed a significantly lower rate of sphincter-preserving surgery (73% vs 86%; $P = .028$). Time from diagnosis to surgery in this group was also significantly longer (median 272 vs 146 days; $P < .0001$).

Conclusion: Patients undergoing surgery for rectal cancer during the first year of the COVID-19 pandemic presented later and at a more advanced stage. They were more likely to be treated with total neoadjuvant therapy and were less likely candidates for sphincter-preserving surgery.

Introduction

In March of 2020, the World Health Organization declared the novel COVID-19 outbreak as a global pandemic.[1] In an attempt to contain the spread of the virus and to preserve medical resources, including mechanical ventilators, intensive care unit beds, and designated healthcare personnel, many surgical societies, institutions, and government officials recommended postponing nonemergency operations.[2–4] Consequently, surgical care in the United States was limited to emergency and urgent oncological cases. In addition, social distancing and other restrictions contributed to a significant decrease in elective colorectal operations and screening colonoscopies around the world.[5–7]

Treatment of rectal cancer has significantly evolved in recent decades with the introduction of preoperative neoadjuvant treatment and surgical techniques designed to enable anal sphincter preservation and local excision (rectal-preserving surgery) for low-lying rectal tumors. The current paradigm of rectal cancer treatment takes into consideration not only optimal cure rates but also functional outcomes in addition to morbidity and mortality considerations. The widespread implementation of neoadjuvant chemoradiotherapy (CRT) has led to tumor shrinkage, allowing for a higher rate of sphincter-preserving operations with increased rates of negative margins and reduction in lymphovascular invasion as seen in the surgical specimen.[8–11] Total neoadjuvant therapy (TNT), a promising treatment strategy that incorporates chemotherapy with CRT before surgery, was originally described

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for poor-risk rectal cancers.[12] It has recently been added to the National Comprehensive Cancer Network (NCCN) clinical guidelines as an alternate treatment strategy for locally advanced rectal cancer.[13] It theoretically offers several surgical advantages, such as increasing the possibility of performing a sphincter-sparing operation and potentially lowering the odds of requiring an ileostomy. Nonetheless, neither of these theoretical advantages were upheld in a recent meta-analysis, suggesting that the benefit remains mainly in disease control and decreased recurrence rates.[14] Nevertheless, appropriately treating rectal cancer requires extensive preoperative planning, multidisciplinary team meetings (MDTs), administration of preoperative treatments, and considerable operating room resources and staff. These evidence based practice measures are well described in the standards of the Commission on Cancer National Accredited Program for Rectal Cancer (NAPRC).[15] Since the pandemic was declared in March 2020, all these crucial resources have been limited. One of the main global healthcare concerns was the indirect effects of healthcare changes and social distancing caused by the pandemic, causing patients to present with advanced malignancies due to the lack of proper screening and access to healthcare services.[16,17] In patients diagnosed with rectal cancer, this could potentially manifest as a decline in the rate of sphincter-preserving operations and a commensurate increase in the prevalence of abdominoperineal excisions.

We hypothesized that rectal cancer treatment was significantly impacted by the COVID-19 pandemic. To assess this impact, we retrospectively reviewed the trend in oncological operations performed on newly diagnosed rectal cancer patients in our institution during the first year of the COVID-19 pandemic.

Methods

A retrospective review of a prospectively maintained institutional review board-approved database at an NAPRC-accredited referral center was performed after institutional review board approval (FLA 20–048). Patients undergoing surgery for newly diagnosed rectal cancer during the period between 2016 through 2021 were included and divided into 2 groups. Patients operated during the first year of the COVID-19 pandemic (March 2020–February 2021) comprised the COVID-19–era study group, whereas patients operated earlier (March 2016–February 2020) were allocated to the pre–COVID-19 control group. Clinical staging was determined by pelvic magnetic resonance imaging (MRI) using a rectal cancer scan protocol. Patients with T3 and T4 clinical staging, as defined by a pelvic MRI, were considered to have locally advanced disease. All patients were discussed at a weekly institutional NAPRC-accredited rectal cancer MDT, and all decisions were made in adherence to current NCCN clinical practice guidelines.[13] No patients were referred for longer treatment protocols, such as TNT, due to limitations or restrictions caused by the pandemic, as all decisions were based solely upon oncological considerations. Patients who presented with liver or lung metastases before surgery (synchronous presentation) detected by routine CT scan of the chest, abdomen, and pelvis, or by positron emission tomography/CT scan, who underwent surgery for rectal cancer following an MDT consensus decision, were also included in our study.

Time of diagnosis was defined as the date of the endoscopic procedure on which a diagnostic biopsy was obtained showing histopathological evidence of rectal cancer. The primary outcome measure was the rate of sphincter-preserving operations compared to abdominoperineal resection (APR) for rectal cancer. Sphincter-preserving operations included transanal local excision and low anterior resection (LAR) with restorative proctectomy or coloanal anastomosis. Non–sphincter-preserving surgery entailed APR with a permanent colostomy. This study did not include patients with active infection of COVID-19.

Statistical analysis

Univariable analysis was used to compare the patients' characteristics between the control and study groups, in which the χ^2 analysis or Fisher exact test, as appropriate, was used for categorical variables, while two-sample t test was conducted for continuous variables. To compare the outcomes between the control and study groups, a Poisson model was performed to assess rate differences, and the Wilcoxon rank sum test was utilized to test the difference in the time to surgery or treatment. All data analyses were conducted using SPSS version 20.0 (IBM Corp, New York, NY).

Results

Two hunderd and thirty four patients with rectal cancer were included in the study, and the distribution of rectal cancer operations throughout the study period, including both APR and sphincter-preserving surgery, is depicted in Figure 1**.** The pre–COVID-19 control group included 180 (77%) patients, and the COVID-19–era study group comprised 54 (23%) patients. Patients' demographics and clinical data showed no significant differences between the 2 groups in terms of mean age (60.0 ± 12.7 vs 60.6 ± 12.7 years; $P = .7648$), sex ($P = .3170$), or body mass index (26.6 ± 4.8 vs. 27.4 ± 4.6 kg/m^2; $P = .2580$) (Table I). In addition, the American Society of Anesthesiologists grade was compatible between the 2 groups. However, we noticed a significant difference ($P = .02$) in clinical T stage presentation: patients in the COVID-19–era group presented with a significantly higher rate of 79% (41 patients) for stage T3/T4 compared to the pre–COVID-19 group, presenting with a rate of 58% (103 patients). Furthermore, more patients in the COVID-19–era group presented with metastatic disease compared to the pre–COVID-19 group (9% vs 3%; $P = .05$). These findings also translated to a higher percentage of patients presenting with more advanced tumor MRI findings, including sphincter involvement (25% vs 13%, $P = .04$) and positive circumferential resection margins, although the latter difference did not achieve statistical significance. In the pre–COVID-19 group, 35% of patients underwent surgery without receiving any neoadjuvant therapy, compared to only 24% in the COVID-19–era study group (35% vs 24%, $P = .14$). Significant differences were found regarding the type of neoadjuvant treatment, with 50% of patients in the pre–COVID-19 group receiving CRT and only 15% treated with TNT. This compared to the COVID-19–era group in which only 24% of patients underwent traditional neoadjuvant CRT compared to 52% patients who received TNT ($P = .0001$).

In the pre–COVID-19 group, 155 patients underwent sphincter-preserving operations (including 141 LAR and 14 transanal local excisions), and 25 patients underwent APR. In the COVID-19–era group, 38 patients underwent sphincter-preserving operations (36 LAR and 2 transanal local excisions), and 14 patients underwent APR. When comparing outcomes between the 2 groups, patients in the COVID-19–era group had a significantly lower rate of sphincter-preserving surgery (73% vs 86%; $P = .028$). A flowchart outlining the treatment pathways and key results of this study is detailed in Figure 2.

Time to treatment (from diagnosis to initiation of any treatment modality) was significantly prolonged in the COVID-19–era group (11.1 vs 8.7 weeks, $P = .006$). In addition, the median time from diagnosis to surgery in the COVID-19–era group was significantly longer compared to the pre–COVID-19 group (9.5 vs 5 months; $P < .0001$). After stratifying patients who underwent TNT protocol treatment, the median time from diagnosis to surgery for patients

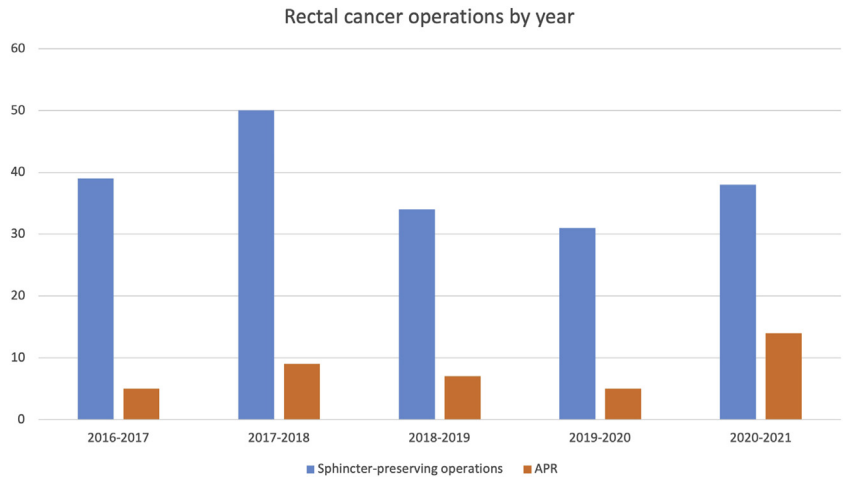

Figure 1. Rectal cancer operations by year. *APR,* abdominoperineal resection.

Table I
Comparison of characteristics between control and study group

	Control ($n = 180$)	Study ($n = 54$)	*P* value
Age, mean ± SD, y	60.0 ± 12.7	60.6 ± 12.7	.76
Female sex, n (%)	60 (33.3)	22 (40.7)	.31
BMI, mean ± SD	26.6 ± 4.8	27.4 ± 4.6	.25
ASA, n (%)			.50
1	3 (1.7)	0 (0.0)	
2	103 (57.5)	28 (51.9)	
≥3	73 (40.8)	26 (48.1)	
MRI findings			
Tumor location, n (%)			.4889
Low rectum	80 (44.44)	29 (53.7)	
Middle	80 (44.44)	20 (37.0)	
Upper	20 (11.11)	5 (9.3)	
Clinical T staging, n (%)			.02
1	20 (11.2)	3 (5.8)	
2	55 (30.9)	8 (15.4)	
3/4	103 (57.9)	41 (78.8)	
Clinical N staging, n (%)			.41
0	92 (51.1)	23 (45.1)	
1	74 (41.1)	26 (51.0)	
2	14 (7.8)	2 (3.9)	
Clinical M staging, n (%)			.05
0	175 (97.2)	48 (90.6)	
1	5 (2.8)	5 (9.4)	
Sphincter involvement, n (%)	24 (13.3)	13 (24.5)	.04
Positive CRM, n (%)	46 (25.6)	17 (31.5)	.38
Upfront surgery, n (%)	63 (35)	13 (24)	.14
Neoadjuvant treatment, n (%)	117 (65)	41 (76)	.0001
CRT	90 (50)	13 (24)	
TNT	27 (15)	28 (52)	

ASA, American Society for Anesthesiologists; *BMI,* body mass index; *CRM,* circumferential resection margins; *CRT,* Chemoradiotherapy; *MRI,* magnetic resonance imaging; *SD,* standard deviation; *TNT,* total neoadjuvant therapy.

treated with TNT in the COVID-19–era group was also significantly longer compared to patients treated with TNT in the pre–COVID-19 group (10.5 vs 9 months; $P = .0118$), while the time from diagnosis to surgery for patients without TNT in the COVID-19–era group was also longer but not statistically significant (median months: 5.5 vs 4.5; $P = .3614$). Surprisingly, no significant differences were seen in the abdominal surgical approach techniques used between the 2 groups or in the rate of patients who underwent transanal total mesorectal excision surgery. Review of the pathology specimens demonstrated no significant differences in pathologic TNM staging, the number of harvested lymph nodes, or total mesorectal excision quality (Table II).

Discussion

Colorectal cancer is the second leading cause of cancer death in the United States. In 2021, it was estimated that there would be 149,500 new cases of colorectal cancer, with more than 50,000 related deaths.[18] Current treatment of rectal cancer is characterized by a multidisciplinary approach; the successful management of this malignancy relies greatly on early screening and diagnosis as it directly affects prognosis. These unprecedented times, brought upon by the COVID-19 pandemic, had a dramatic effect on healthcare. Resources have been abridged, and social distancing has been widely implemented to try and minimize exposure for both

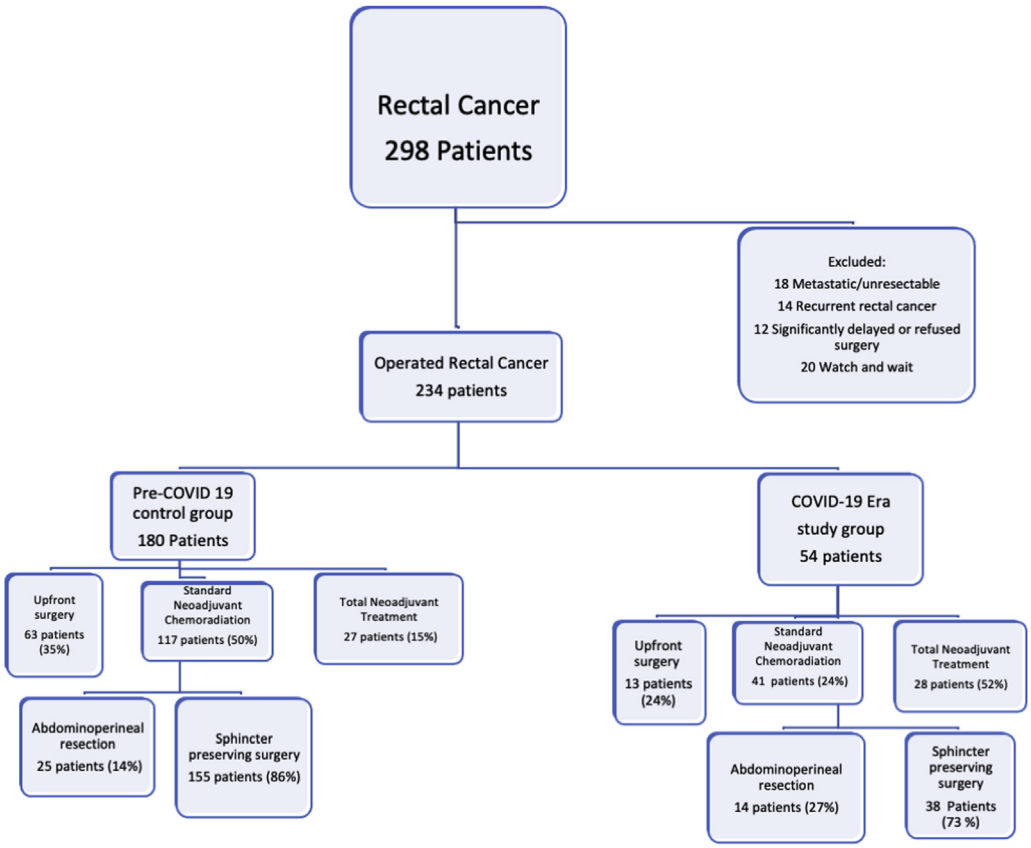

Figure 2. Study flow diagram. A flowchart outlining the treatment pathways and key results of rectal cancer patients before and during the first year of the COVID-19 pandemic.

Table II
Surgical data, surgical outcomes, and pathology results

	Control ($n = 180$)	Study ($n = 54$)	*P* value
Abdominal approach, n (%)			.83
Laparoscopy	139 (84)	43 (83)	
Open surgery	27 (16)	9 (17)	
TaTME, n (%)	97 (54)	28 (52)	.7924
Procedure, n (%)			.028
Sphincter preserving surgery	155 (86)	38 (73)	
Abdominoperineal resection	25 (14)	14 (27)	
Time to initiation of treatment, wk (SD)	8.7 (5.4)	11.1 (6.2)	.0068
Time (diagnosis to surgery), median (IQR value), mo			
Overall	5 (5)	9.5 (6)	<.0001
Patients with TNT	9 (1.5)	10.5 (3.5)	.0118
Patients without TNT	4.5 (3.5)	5.5 (6)	.3614
Pathological staging:			
T, n (%)			
0	38 (21.1)	16 (29.6)	.2829
1	29 (16.1)	8 (14.8)	
2	48 (26.7)	15 (27.8)	
3	61 (33.9)	12 (22.2)	
4	4 (2.2)	3 (5.6)	
N, n (%)			
0	127 (70.6)	41 (75.9)	.8124
1	38 (21.1)	9 (16.7)	
2	15 (8.3)	4 (7.4)	
M, n (%)			
0	176 (97.8)	52 (96.3)	.6239
1	4 (2.2)	2 (3.7)	
TME grading, n (%)			.2229
Complete	119 (71.2)	31 (59.6)	
Near	27 (16.2)	10 (19.2)	
Incomplete	21 (12.6)	11 (21.2)	
Number of lymph nodes, median (IQR value)	24 (15.5)	24 (14.0)	.8489

APR, abdominoperineal resection; *taTME,* transanal total mesorectal excision; *IQR,* interquartile range; *SD,* standard deviation; *TNT,* total neoadjuvant therapy; *TME,* total mesorectal excision.

patients and surgeons, resulting in delaying surgery and a massive decrease in case volume.[19,20]

It appears that the comprehensive network of multidisciplinary care for rectal cancer has been substantially adversely affected by the COVID-19 pandemic, as seen by the statistically significant decrease in sphincter-preserving operations during the first year of the pandemic. We believe this to be a sensitive parameter of delayed diagnosis and treatment. These findings are further supported by the fact that the patients operated on during the pandemic presented with more advanced disease and worse findings on their initial imaging evaluation. This may be attributed to the lack of timely screening colonoscopies performed during the pandemic.[21] Conversely, these findings cannot only be explained by delayed diagnosis, as patients operated on during the pandemic year had a significantly longer duration of time from diagnosis to surgery compared to the pre–COVID-19 group. Although this fact can be possibly attributed to the prolonged time to initiation of any treatment seen in the COVID-19 group (11.1 vs 8.7 weeks, $P = .006$), and even though this 2-week difference represents a true delay in the initiation of treatment, it is unlikely to completely explain the significant difference seen in sphincter-preserving operations between the 2 groups. Furthermore, a multicenter study recently published reviewing over 1,000 patients with rectal cancer has shown that delay in the initiation of treatment beyond the NAPRC's recommended 60 days from diagnosis does not significantly affect oncologic outcomes.[15,22]

The proportion of patients who received TNT in the COVID-19–era group was significantly higher than in the control group. This finding may not be surprising given the fact that these patients presented with a higher rate of locally advanced cancer at a time when surgical treatment was unavailable or delayed. These results are also consistent with the recent categorization of TNT as a viable treatment strategy for locally advanced rectal cancer by the NCCN.[13,23] Consequently, this practice has been adopted and increasingly employed at our institution in recent years, evidently surpassing the traditional approach of preoperative CRT followed by postoperative adjuvant chemotherapy in the first year of the pandemic. Unfortunately, the much higher rate of patients undergoing TNT did not translate into a reduction in sphincter-preserving surgery. This result corresponds with the findings of a recent meta-analysis that failed to see an increase in sphincter-preserving surgery in patients undergoing TNT.[14] The higher proportion of patients undergoing TNT in the COVID-19–era group may account, at least in part, for the longer duration of time from diagnosis to surgery in this group. However, after stratifying for TNT, the time from diagnosis to surgery for patients with TNT in the COVID-19–era group remained significantly longer compared to patients with TNT in the pre–COVID-19 group. This indicates that the time from diagnosis to surgery has become longer during the pandemic, regardless of the therapeutic strategy. Bearing in mind that during the first year of the pandemic, at least in our institution, outpatient oncology clinic activity remained open, and neoadjuvant treatments remained readily available, even at times when definitive surgical management was delayed, other factors that may have potentially contributed to this delay. Whether surgeons' fear of poor results, complications, and anastomotic leaks have also played some role in delaying surgery is yet to be determined.[24] We do, however, wish to emphasize, in that aspect, that the decision regarding the appropriate oncological operation, including whether to perform a sphincter-preserving operation or an APR, was based solely on oncological considerations as discussed during the presentation of every patient with rectal cancer during our weekly institutional MDT meeting. In any event, a longer process of diagnosis and treatment is associated with significantly increased healthcare costs and utilization.[25] Further studies are needed to determine to what extent, if any, this delay may affect oncological outcomes.

During the outbreak of the pandemic, there was concern about COVID-19 transmission during laparoscopic surgery.[26,27] A recent study from China noted that the rate of laparoscopic surgery dropped by nearly 20% in patients operated on during the COVID-19 era.[28] However, we saw no significant differences between the rate of minimally invasive and open surgery in our study. It seems that the initial concern of COVID-19 transmission did not translate into a surge in open surgery cases at our institution, where adherence to the American College of Surgeons guidelines on resumption of elective surgical care was routinely practiced[29] as elective surgery activity resumed. Patients were routinely screened before surgery for respiratory symptoms together with assessment of fever, travel, occupation, and contact with known or suspected individuals with COVID-19. In addition, all operated patients were tested for COVID-19 before surgery to further minimize the risk of exposure to the surgical team. There was a designated operating room reserved for patients with an active diagnosis of COVID-19, and if clinically appropriate, those patients were operated upon late in the day after operations on COVID-19 free patients were completed. However, this scenario was not a factor to this study.

Our study has several limitations, mainly its nonrandomized retrospective single-center nature and the lack of long-term oncological outcome follow-up. Although our cohort is relatively small, it is mainly due to the dramatic decrease in case volume during the COVID-19 pandemic. Despite these limitations, we believe our findings indicate a concerning trend that should be considered when mobilizing healthcare resources in the future.

In conclusion, it appears that shifting resources toward controlling the COVID-19 pandemic has not gone without other significant adverse costs. Patients with rectal cancer presented at a later and more advanced stage and paid a price with a higher rate of non–sphincter-preserving operations. This knowledge requires us to be more diligent in screening and to strive to appropriately reduce diagnosis to surgery time. Our study highlights an important lesson about continued medical care in uncertain times. Although future pandemics might represent differently than COVID-19, we must not forget that significant delays in screening and diagnosis of malignant diseases can have a significant impact on the quality of life and survival of patients. In future airborne pandemics, we need to remember that continuous care and patient reassurance are feasible when using appropriate safety measures, including personal protective equipment, pre-procedure testing, and promoting widespread vaccination, if available.[5] In addition, high-risk subgroups should be targeted to double the colonoscopy yield of successful diagnosis.[30] In relation to delaying treatment, bed and staff availability should be maintained as much as possible by having local transfer programs set in place and employing models for predicting hospital admissions and bed occupancy during the next waves of this or any future pandemic.[31] In addition, prioritizing oncologic procedures and treatments over procedures performed for non-malignant indications should allow for prompt and timely surgical intervention. Successful acomplishment of this task will become more challenging as there is a backlog of patients with rectal cancer whose care will further strain an already burdened healthcare system still dealing with the pandemic.[32] Long-term oncological outcomes will need to be reviewed in the future to further elucidate the impact of the COVID-19 pandemic on rectal cancer treatment.

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Conflicts of interest/Disclosure

The authors have no related conflicts of interest to declare. SDW is a consultant for ICON language services, Intuitive Surgical Styker, Medtronic,Takeda, ARC/Corvus, Astellas, Baxter, Olympus, AIS Channel, Livsmed, GI Supply, Leaading Biosciences, has stock options for Regentys, LifeBond, Pragam/GibLib, Renew Medical, and royalties for Medtronic, Intuitive Surgical, Karl Storz Endoscopy America Inc., Unique Surgical Innovations LLC.

Dedication

In loving memory of Prof. Herbert R. Freund MD.

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