Original Article

Comparison of Clavien-Dindo and Common Terminology Criteria for Adverse Events Classifications in Postoperative Early-Stage Complications of Patients with Colorectal Cancer

Kolorektal Kanserli Hastaların Postoperatif Erken Dönem Komplikasyonlarında Clavien-Dindo ve Common Terminology Criteria for Adverse Events Sınıflamalarının Karşılaştırılması

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ABSTRACT

Introduction: The present study aimed to compare early complication rates, risk factors for complications, and hospital stay lengths in patients operated on for Colorectal cancer, by using Clavien-Dindo and Common Terminology Criteria for Adverse Events (CTCAE) complication classifications.

Materials and methods: 222 patients who were operated between March 2019 and June 2020 with the diagnosis of colorectal cancer and had early complications were evaluated retrospectively. Complications that developed in the early postoperative period were graded according to Clavien-Dindo and CTCAE classifications.The effects of demographic data, surgical technique, tumor location, neoadjuvant chemoradiotherapy history, preoperative transfusion history, urgency of the operation, additional organ resection, co-morbid diseases, pathological stage and duration of surgery on complications were compared.

Results: According to the Clavien-Dindo classification, the risk of developing complications was 3 times higher in male gender, 8 times higher in open surgical intervention, and 1.7 times higher in diabetes mellitus. According to the CTCAE classification, performing liver resection in the same session increased the risk of complications 5 times, while the use of open surgical technique increased the risk 8 times.

Discussion: Neither classification system is superior to the other in grading postoperative complications, and both can be used to rate surgical complications.

Keywords: Colorectal cancer, surgical,complication,Clavien-Dindo,CTCAE

ÖZET

Giriş: Kolorektal kanser tanısı ile opere edilen hastalarda Clavien-Dindo ve Common Terminology Criteria for Adverse Events (CTCAE) komplikasyon sınıflamaları kullanılarak, erken dönem komplikasyon oranları, komplikasyon oluşmasındaki risk faktörleri ve hastanede kalış sürelerinin karşılaştırılması amaçlandı.

Gereç ve yöntemler: Mart 2019 ve Haziran 2020 tarihleri arasında kolorektal kanser tanısıyla operasyona alınan, erken dönem komplikasyon gelişen 222 hasta retrospektif olarak değerlendirildi. Postoperatif erken dönemde gelişen komplikasyonlar, Clavien-Dindo ve CTCAE sınıflamalarına göre derecelendirildi. Hastaların demografik verilerinin, ameliyat tekniğinin, tümör yerleşiminin, neoadjuvan kemoradyoterapi öyküsünün, peroperatif transfüzyon öyküsünün, operasyonun aciliyeti, ek organ rezeksiyonunun, yandaş hastalıkların, patolojik evre ve ameliyat süresinin komplikasyon üzerine etkisi karşılaştırıldı.

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Bulgular: Clavien-Dindo sınıflamasına göre erkek cinsiyet 3 kat, açık cerrahi girişimde 8 kat ve diabetes mellitusta 1.7 kat komplikasyon gelişme riski daha fazla bulundu. CTCAE sınıflamasına göre aynı seansta karaciğer rezeksiyonu uygulanması komplikasyon riskini 5 kat, açık cerrahi teknikte risk 8 katına çıkmıştır.
Tartışma: Postoperatif komplikasyonları derecelendirirken iki sınıflama sisteminin birbirine üstünlüğü olmayıp, her ikisi de cerrahi komplikasyonları derecelendirmede kullanılabilir.

Anahtar kelimeler: Kolorektal kanser, cerrahi, komplikasyon, Clavien-Dindo, CTCAE

Introduction

Colorectal cancers are both the most common cancer types among gastrointestinal system cancers and the most cured cancer types after treatment [1]. Postoperative complications after colorectal cancer surgery occur in up to 50% of patients.They prolong hospital stay, increase hospital costs, increase mortality, and delay adjuvant treatments.To date, many classification systems have been used for the grading and standardization of postoperative complications in malignant patients.There is a need for an applicable complication classification that standardizes the treatment results of applications between different centers or different clinical applications in the same center. Clavien-Dindo and Common Terminology Criteria for Adverse Events (CTCAE) are frequently used methods and their parameters can be used together if necessary [2,3].

The Clavien classification was first used in 1992 [4].It was updated as the Clavien-Dindo classification in 2004 due to the lack of detailed treatment of complications and the inadequacy of evaluating permanent complications [2]. In the Clavien-Dindo classification, only five grades of post-operative complications are defined.In addition, Clavien-Dindo does not provide an organ-specific classification and does not consider pre-existing conditions and co-morbidities that play an important role in the occurrence of complications.

Standardized and published by the National Institutes of Health (NIH) and the National Cancer Institute (NCI), CTCAE is a classification system used to define the severity of organ toxicity for patients undergoing cancer treatment. This system is widely used to evaluate and describe the toxicity of chemotherapy or radiotherapy. It also describes side effects that result from intraoperative and postoperative complications. In 2009, CTCAE version 4.0 was revised to include significantly more surgical complications. However, it still lacked some common surgical complications [5]. The final version of this system, which also rates complications, was released in April 2018 [3].

In the present study, we grouped complications after colorectal cancer surgery according to Clavien-Dindo and CTCAE classifications. The aim of the study was to investigate the risk factors for complications and the differences between the two classification methods.

Material and Method

Setting and Participants

In the present study, 222 patients were analyzed retrospectively. All of the participants consisted of patients who were operated on with the diagnosis of colorectal cancer between March 2019 and June 2020 at the SBU Ankara Oncology SUAM General Surgery and Surgical Oncology Clinic.

Patients who were operated for colorectal malignancy recurrence, patients younger than 18 years of age, patients who underwent intervention for benign reasons and were considered inoperable and pregnant women were excluded from the study.

Data Collection

Data collected and recorded from patients included: patients' age, gender, comorbidities, body mass index, previous abdominal surgery, preoperative treatments, duration of operation, postoperative stage, operation performed, presence of ostomy, simultaneous liver resection, intraoperative complications, perioperative blood transfusion, early postoperative complications (post-op 30 days), need for reoperation and intensive care, number of days of hospitalization, post-operative 30-day mortality file data. Co-morbidities were divided into five groups as follows: cardiac diseases, diabetes mellitus, chronic obstructive pulmonary disease, other chronic diseases and no comorbidities. The cardiac group consisted of patients with a history of hypertension or previous ischemic cardiac heart disease. Patients receiving treatment for the diagnosis of type I-II diabetes were included in the diabetes group. On the other hand, patients with chronic obstructive pulmonary disease diagnosis in pre-operative evaluation or history formed the COPD group. The patients were divided into 2 groups as 65 years of age and older and under 65 years of age. Body mass index was grouped into two groups as below 30 and above 30. Tumor location was defined as right colon, up to the cecum and distal transverse colon. Tumor localization in the colon segments containing the sigmoid colon from the distal transverse colon was grouped as the left colon. Tumors at a distance of up to 15 cm from the anal canal seen in colonoscopy examination were included in the rectal cancer group. Patients with and without ileostomy and colostomy were considered as two separate groups. Postoperative staging was divided into three groups as stage 0-1-2, stage 3 and stage 4. Postoperative complications were evaluated separately in Clavien-Dindo and CTCAE classifications. Complications of I-II degree, not life-threatening and not requiring surgical or interventional procedures were evaluated in one group in both classifications. Serious complications of III-IV and V degrees, which were operated urgently, required intensive care and resulted in the patient's exitus, were examined under the second group.

Statistical Analysis

SPSS 21 statistical program was used in the statistical analysis of the data. (IBM SPSS Statistics Version 21, International Business Machines Corporation, Armonk, USA).

In the study, mean, standard deviation, median, minimum and maximum values are given for numerical type variables as descriptive statistics, while numbers and percentages are given for qualitative categorical data. Both numerical and categorical variables were compared with each other in terms of the degree of complication. After testing the data for that difference, the homogeneity of the distributions was evaluated. Afterwards, Student's t test and ANOVA were used for numeric variables in independent groups, and chi-square or Fisher exact test was used for categorical variables. A value of $p<0.05$ was accepted as a criterion for statistical significance. A multiple logistic regression model was established to determine the independent parameters affecting the degree of complication, and the odds ratios were given together with the confidence intervals. Our study was conducted in accordance with the Declaration of Helsinki and was approved by ethics committee of SBU Ankara Oncology SUAM (2022-01/32).

Results

The patients who underwent surgery consisted of 131 men (59%) and 91 women (41%). The median age of the patients was 64 (with the youngest being 28 and the oldest being 90). There was tumor localization in the right colon in 41 (18.5%) patients. Left colon group

Table 1. Demographics and clinical characteristics of patients

Age(years)	Median	64
	Range	28-90
	<65	112 (50.5%)
	≥65	110(49.5%)
Sex	Female	91 (41%)
	Male	131 (49.5%)
Body mass index (kg/m^2)	Median	25
	Range	19-32
	<30	180 (81.1%)
	≥30	42 (18.9%)
Tumor location	Right	41 (18.5%)
	Left	79 (35.6%)
	Rectum	102 (45.9%)
Previous abdominal operation		47 (21.2%)
Technique	Laparoscopic	106 (47.7%)
	Open	116 (52.3%)
Ostomy		91(41%)
Liver resection		11 (5%)
Emergency surgery		22 (9.9%)
Preoperative transfusion		9 (4.1%)
Neoadjuvant therapy		69 (31.1%)
Operative time	Median	145
	Range	90-325
	<150 minutes	117 (52.7%)
	≥150 minutes	105 (47.3%)
ASA	1	0
	2	124 (55.9%)
	3	95 (42.8%)
	4	3 (1.4%)
Stage	0-2	135 (60.8%)
	3	73 (32.9%)
	4	14 (6.3%)
Comorbid diseases	Cardiac	68 (30.6%)
	Copd	17 (7.7%)
	Dm	15 (6.8%)

ASA: American Society of Anesthesiologists, COPD: chronic obstructive lung disease dm: diabetes mellitus

consisted of 79 patients (35.6%). There were 102 patients (45.9%) in the rectal group.

Laparoscopic intervention was performed in 106 (47.7%) of the patients. The characteristics of all patients are included in Table 1.

Intraoperative complications occurred in four (1.8%) patients. During the operation, small bowel repair was performed in three patients and ureter repair was performed in one patient. Thirty (13.5%) patients were re-operated due to postoperative complications. Seven of these patients underwent surgical intervention due to surgical site infection. Three patients were re-operated for evisceration. Twelve patients were re-operated due to anastomotic leakage and deterioration in clinical follow-ups.Five patients were operated because complications related to ileostomy or colostomy developed. One patient was operated on due to bleeding the next day after surgery. Two patients were re-operated because of early-stage ileus. Twenty-nine (13.1%) of the patients were followed up in the surgical intensive care unit due to the deterioration of the general condition in their clinical follow-ups. The patient, who was re-operated on the third postoperative day due to the development of anastomotic leakage, was exitus one day later on the day of reoperation. The patient was re-operated on the 20th postoperative day, due to the development of ileus in the clinical follow-ups, which was performed concomitantly with surgery due to liver metastasis of rectum cancer. The patient was exitus on the 21st day of hospitalization due to the development of cardiac arrest. The patient, who was operated for colon cancer and underwent massive intraoperative transfusion, was exitus on the same day after the operation. Three patients (1.4%) were exitus within thirty days post operation.

Wound infection developed in 49 (22%) patients operated for colorectal cancer. 27 patients (12.1%) with complaints of nausea were treated medically. Intravenous or oral replacement was given to 43 patients (19.3%) due to electrolyte imbalance. Medical treatment was given to 34 patients (15.3%) due to pain. Seven patients (3.1%) were treated for high blood pressure. Two patients (0.9%) developed post-surgical mycord infarction. Three patients (1.3%) developed

Table 2. Postoperative complications and their classification

	N (%) median (range)
Patient with intraoperative complications	4 (1.8%)
Re-operated patient	30 (13.5%)
Patients needed ICU care	29 (13.1%)
30-day mortality	3 (1.4%)
Clavien-Dindo classification grade	
1	0
2	161(72.5%)
3A	13(5.9%)
3B	14(6.3%)
4A	20(9%)
4B	11(4.9%)
5	3(1.4%)
CTCAE complication grade	
G1	0
G2	162(73%)
G3	36(16.2%)
G4	21(9.5%)
G5	3(1.4%)
Hospital stay length(days)	
Median	8
Range	1-37

CTCAE: common terminology complication advers event,ICU: intensive care unit

neurological deficits. Two patients (0.9%) experienced delirium. Respiratory distress occurred in five patients (2.4%) during their clinical follow-up. Replacement was performed in eight patients (3.6%) due to low hemoglobin associated with surgery. Acute renal failure developed in five patients (2.4%). Postoperative fistula occurred in four patients (1.8%). Evisceration occurred in three patients (1.3%). Anastomotic leakage occurred in 16 patients (7.2%) after surgery, and 12 of these patients were re-operated. Complications related to ileostomy and colostomy developed in five patients (2.4%), and these patients were re-operated. Post-operative ileus was seen in nine patients (4%) and two patients were re-operated.

Complication rates in complication classification systems are shown in Table 2.

The relationship between the length of hospital stay evaluated in the present study and the degree of complication of the Clavien-Dindo and CTCAE classifications was found to be statistically significant (p=0.0001).It was observed that as the degree of complication increased, the length of stay in the hospital also increased. No difference was observed between the increase in age, BMI and operative time, and the degree of complications (Table 3). The evaluation of the parameters affecting the Clavien-Dindo classification in multivariate analysis showed that the risk of complications is significantly higher in patients with male gender, open surgery and diabetes mellitus. The risk of developing complications was 3 times higher in males, 8 times higher in open surgery, and 1.7 times higher in diabetes mellitus (Table 4).

In the multivariate analysis performed for the CTCAE classification, it was seen that performing liver resection in the same session increases the risk of complications 5 times. Likewise, the risk increased 8 times in the open surgical technique (Table 5).

Table 3. Comparison of complication classifications

	Clavien-Dindo		CTCAE	
	1-2	3-4-5	2	3-4-5
Age (mean±SD)	63.9±11.2	66.5±10.7	63.8±11.2	66.8±10.7
BMI (mean±SD) (kg/m$^{2)}$	25.8±2.7	27.6±3.12	25.8±2.7	25.5±3
Operation time (minute) (mean±SD)	156.2±43.4	165.8±47.8	156.4±44.1	163.5±45.1
Hospital stay (mean±SD) (day)	7.8±2.7*	15.1±7.3*	7.6±2.3*	14.3±7.0*
*p=0.0001				

SD: standart deviation, BMI: body mass index, CTCAE: common terminology complication advers event

Table 4. Multivariate Logistic Regression analysis of risk factors related Clavien-Dindo classification

Parameter	p	OR	95% CI
Male	0.006	3	1.37-6.58
Open Technique	0.0001	8	3.39-19
Diabetes Mellitus	0.014	1.7	1.1-2.7

OR:odds ratio,CI:confidence interval

Table 5. Multivariate Logistic Regression analysis of risk factors related CTCAE classification

Parameter	p	OR	95% CI
Liver resection	0.023	5.1	1.2-21.1
Open Technique	0.0001	8	3.39-19

CTCAE: common terminology complication advers event,OR:odds ratio,CI:confidence interval

Discussion

The present study examined the compatibility and differences of two different complication classification systems in colorectal cancer surgery. 222 patients who were classified for colorectal surgery complications with Clavien-Dindo and CTCAE were analyzed. Complications developed in four patients (1.8%) during the operation. Mortality occurred in three patients (1.4%) during the first 30-day follow-up after surgery. In their clinical follow-up, 30 patients (13.5%) were re-operated. In the study of Zawadki et al., 445 patients who underwent surgery with the diagnosis of colorectal cancer were examined. In this study, 51 patients were re-operated. 20 patients were re-operated for anastomotic leakage, eight patients due to bleeding, five patients due to wound dehiscence. 18 patients who were re-operated were not grouped under a special heading[6].The median length of stay in hospital was eight days. It was determined that, according to both classification systems, the hospitalization time increases as the degree of complication increases. In addition, open surgical technique is a risk factor for the development of complications according to both classification systems. Male gender and diabetes mellitus were found to be additional risk factors in the Clavien-Dindo classification. In the CTCAE classification, the risk of developing complications increased in the liver resection group. It can be said that there are similarities and differences in the two classification systems in examining the factors that cause the development of complications. Age is an independent risk factor for both morbidity and mortality compared to other comorbidities [7].

In this study to rate complications after surgery for colorectal malignancy, the cut-off value for age was 65. In our study, the degree of complications was observed to increase with increasing age. However, there was no statistically significant difference between the degree of complication and age.

Another factor in terms of complications is obesity. Obesity not only makes the procedure more technically demanding and potentially longer, but also increases the risk of developing wound infection. Recent studies have examined the relationship between obesity and surgical site infection after colorectal surgery. These studies reported that patients with a BMI above 30 kg/m^2 had an increased surgical site infection [8]. There are also publications reporting that BMI is an independent risk factor for anastomotic leakage [9]. In the present study, the complication degree of BMI was compared, but no statistically significant result was determined.

One of the factors affecting both the surgery to be performed on the patient and the postoperative follow-up is the existing comorbidities of the patient. Due to comorbidities, the wound healing of the patient changes significantly and the severity of the complication may increase accordingly. Poor glycemic control caused an increase in the incidence of surgical site infections in the early postoperative period in patients undergoing colorectal surgery [10]. In our study, both classification systems were examined and it was observed that diabetes constitutes approximately twice the risk of developing complications in diabetes mellitus, according to the Clavien-Dindo classification. No statistically significant risk for diabetes mellitus was found in the CTCAE classification.

In the literature, it has been reported that anastomotic leakage that develops after colorectal surgery is more common in men. It was thought that this might occur as a result of technical difficulties in male patients due to their narrow pelvis [11]. Studies examining the patient group undergoing LAR have observed that male gender is a risk factor for the development of anastomotic leakage [12]. According to the Clavien-Dindo classification, three times more complications were observed in the male gender, but this inference was not detected in the CTCAE classification.

15-20% of colorectal cancer patients have liver metastases at the time of initial diagnosis. In 70-80% of this patient group, metastasis is limited to the liver only [13-15]. However, some authors stated that simultaneous resection reduces the tumor burden, reduces the economic and psychological burden of patients, and allows patients to undergo a single surgical procedure instead of two [16]. A growing number of authors argue that the optimal operative timing changes gradually from gradual resection to simultaneous resection. In our study, the risk of complications was found to be five times higher in the group with simultaneous liver resection compared to the CTCAE classification. This was not found to be significant in the Clavien Dindo classification.

The use of laparoscopy in surgery for colorectal malignancy is extremely common. Compared to open surgery, laparoscopic surgery has advantages such as smaller incision length, less blood loss and less pain. However, previous studies have shown that laparoscopic surgery has some limitations, such as longer operative time and longer learning curve for surgeons [17, 18]. Laparoscopic surgery is less effective for larger tumors due to traction limitation and consequent insufficient exploration [19]. The incidence of postoperative complications was significantly reduced in the laparoscopic surgery group compared to the open surgery group [20,21]. In our study, open surgery was determined as a risk factor for the

development of complications in the technique.

While some factors that affect the complications that develop after surgery are patient-dependent and cannot be changed, there are also risk factors that can be changed depending on the choice of surgical technique. Laparoscopic surgery performed by experienced colorectal surgeons reduces the postsurgical complication rate.

Conclusion

The present study evaluated complications of colorectal cancer surgery in terms of Clavien-Dindo and CTCAE classifications. It was determined according to both classification systems that as the degree of complication increases, the length of hospital stay also increases. According to both classification systems, open surgery was found to be a risk factor for the development of complications compared to laparoscopic surgery. According to the Clavien-Dindo classification, male gender and diabetes mellitus are other risk factors for the development of complications. According to the CTCAE classification, performing liver resection in addition to open surgery increases the risk of complications. The two classifications have both similarities and differences in revealing the risk factors that cause postoperative complications. There is no superiority between the two classification systems when grading postoperative complications, and both systems can be used to rate surgical complications.

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