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Research Article

Negative impact of COVID-19 pandemia on gastric cancer surgery: Real-life data

COVİD-19 pandemisinin mide kanser cerrahisi üzerine olumsuz etkisi: gerçek yaşam verileri

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Abstract

Aim: In the Coronavirus disease 2019 (COVID-19) pandemic, the primary aim has been social isolation to control the spread of the virus. During this period, the surgery of cancer patients may have been interrupted due to the change in working conditions in hospitals and the postponement of elective surgeries. In this study, the effect of the pandemic on the clinical and surgical characteristics of patients operated for gastric cancer (GC) was investigated.

Material and Methods: Patients who were operated for GC in the general surgery clinic of our hospital between 1 June 2019 and 15 January 2021 and were followed up in the intensive care unit (ICU) during post-operative period were included in the study. Operative patients in the first 9 months of the pandemic (AP) were compared with patients who were operated for GC in the 9 months before the pandemic (BP) by performing a propensity score match analysis. The clinical features, diagnostic methods, surgical characteristics, whether they received neoadjuvant treatment or not, pathological stages at the time of operation,tumor node metastasis (TNM) stage, time from symptom onset to diagnosis, time from diagnosis to operation, post-operative complications, length of hospital stay, and costs were compared.

Results: A total of 55 patients (21 (38.2%) female and 34 (61.8%) male) with a mean age of 65.1±10.7 years and a mean American Society of Anesthesiologists (ASA) score of 2.5±0.5 were included in the study. Twenty-eight (50.9%) of them were operated on BP and 27 (49.1%) were operated on AP. Abdominal pain (89.3% vs 44.4%; p=0.005) and nausea-vomiting (57.1% vs. 18.5%; p=0.010) were more common in the BP group as admission symtoms. The time from symptom onset to cancer diagnosis was longer in AP group (87.5±78.2 vs 175.9±71.2 days; p<0.005). There were more patients receiving neoadjuvant therapy in AP group (44.4% vs 10.7%; p= 0.015); however, the time from neoadjuvant therapy to operation was similar (57.3±34.8 vs 62.8±55.5 days; p=0.441). Considering the pathological TNM stages, the number of stage 3B patients was higher in AP group (33.3% vs. 7.1%; p=0.04). The hospitalization period of the entire study group was 11.4±4.7 days; length of stay in the ICU was 4.7±2.0 days; the median total cost was 11,244.0 TL(The Turkish Lira) [9,443-15,202 TL]; there was no difference between the groups (p>0.05).

Conclusion: In our cohort, COVID-19 pandemic did not make any difference in factors such as diagnostic methods, operation types, surgical complications, length of hospital stay and cost on GC surgery. More patients were referred to neoadjuvant therapy during the pandemic. The pandemic may have led to disease progression as it prolonged the time from symptom onset to diagnosis.

Keywords: COVID-19 pandemic, gastric cancer, neoadjuvant treatment

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Öz

Amaç: Coronavirüs hastalığı 2019 (COVID-19) salgınında öncelikli amaç, virüsün yayılmasını kontrol altına almak için sosyal izolasyon olmuştur. Bu dönemde hastanelerdeki çalışma koşullarının değişmesi ve elektif ameliyatların ertelenmesi nedeniyle kanser hastalarının ameliyatlarına ara verilmiş olabilir. Bu çalışmada pandeminin mide kanseri nedeniyle ameliyat edilen hastaların klinik ve cerrahi özelliklerine etkisi araştırıldı.

Gereç ve Yöntemler: Hastanemiz genel cerrahi kliniğinde 1 Haziran 2019-15 Ocak 2021 tarihleri arasında mide kanseri nedeniyle ameliyat edilen ve ameliyat sonrası dönemde yoğun bakım ünitesinde (YBÜ) takip edilen hastalar çalışmaya dahil edildi. Mide kanseri nedeniyle, pandeminin ilk 9 ayında ameliyat olan hastalar (AP), eğilim skoru eşleşme analizi yapılarak pandemiden önceki 9 ayda ameliyat edilen hastalarla (BP) karşılaştırıldı. Klinik özellikler, tanı yöntemleri, cerrahi özellikler, neoadjuvan tedavi alıp almadıkları, operasyon anındaki patolojik evreleri, tümör lenf nodu metastazı (TNM) evresi, semptom başlangıcından tanıya kadar geçen süre, tanıdan operasyona kadar geçen süre, operasyon sonrası komplikasyonlar, hastanede kalış süresi ve maliyetler karşılaştırıldı.

Bulgular: Yaş ortalaması 65,1±10,7 yıl ve Amerikan Anestezistler Derneği (ASA) skoru ortalaması 2,5±0,5 olan 21 (%38,2) kadın ve 34 (%61,8) erkek olmak üzere toplam 55 hasta çalışmaya dahil edildi. Bunlardan 28'i (%50,9) pandemi öncesi, 27'si (%49,1) pandemi içerisinde ile ameliyat edildi. Başvuru semptomları olarak karın ağrısı (%89,3 vs %44,4; p=0,005) ve bulantı-kusma (%57,1 vs. %18,5; p=0,010) BP grubunda daha sık görüldü. Semptom başlangıcından kanser tanısına kadar geçen süre AP grubunda daha uzundu (87,5±78,2 vs 175,9±71,2 gün; p<0,005). AP grubunda neoadjuvan tedavi alan hasta sayısı daha fazlaydı (%44,4 vs %10,7; p= 0,015); ancak neoadjuvan tedaviden operasyona kadar geçen süre benzerdi (57,3±34,8 vs 62,8±55,5 gün; p=0,441). Patolojik TNM evreleri dikkate alındığında evre 3B hasta sayısı AP grubunda daha fazlaydı (%33,3 vs %7,1; p=0,04). Çalışma grubunun tamamının hastanede kalış süresi ortalama 11,4±4,7 gündü; Yoğun bakımda kalış süresi 4,7±2,0 gün; ortalama toplam maliyet 11.244,0 TL(Türk Lirası) [9.443-15.202 TL]; gruplar arasında fark yoktu (p>0,05).

Sonuç: Kohortumuzda COVİD-19 salgını tanı yöntemleri, ameliyat türleri, cerrahi komplikasyonlar, hastanede kalış süresi ve mide kanseri ameliyatı maliyeti gibi faktörlerde herhangi bir farklılık yaratmadı. Pandemi sırasında daha fazla hasta neoadjuvan tedaviye yönlendirildi. Pandemi, semptomların başlangıcından tanıya kadar geçen süreyi uzattığı için hastalığın ilerlemesine yol açmış olabilir.

Anahtar Kelimeler: COVİD-19 pandemisi, mide kanseri, neoadjuvan tedavi

Introduction

Gastric cancer (GC) is an important cause of mortality and morbidity worldwide. There are more than one million new cases and approximately 769,000 deaths (one in 13 deaths globally) in 2020 [1] . It ranks 5th worldwide in terms of cancer incidence and 4th in terms of cancer-related mortality [1] .

The Coronavirus disease 2019 (COVID-19) caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which started in December 2019 in Wuhan, China and was declared a pandemic by the World Health Organization on March 11, 2020. It has turned into a major pandemic all over the world and has been going on for 2.5 years. As of June 6, 2022, 530,266,292 people have been infected all over the world and 6,299,364 people have died all over the world [2] . With the decisions taken by the Turkish Ministry of Health at the beginning of the pandemis in our country, it was primarily aimed to prevent the spread of this contagious pandemic, with social isolation and closures, hospital elective outpatient clinic applications were reduced and elective surgical procedures were banned for a while in order to reduce the number of affected people. In this period, the surgery of cancer diseases may have been interrupted due to the change in working conditions in hospitals and the postponement of elective surgeries. Some centers have identified cancers that can be safely delayed for several months to manage cancer and have recommended neoadjuvant therapies as an alternative therapy [3] .

Our aim in this study was to investigate the effect of the pandemic on gastric cancer surgery in our center by comparing the patients who were operated for gastric cancer before the pandemic and in the first 9 months of the pandemic.

Material and Methods

Patients who were operated for GC in the general surgery clinic of University of Health Sciences, Ankara Dışkapı Yıldırım Beyazıt Research and Education Hospital between 1 June 2019 - 14 March 2020 [before pandemic (BP)] and 15 March 2020 - 1 December 2020 [after pandemic (AP)] and were followed up in the intensive care unit (ICU) in the post-operative period were included in the study. Considering the date of 14 March 2020, when the pandemic was declared in our country and the precautions were started, the patients who were operated during AP due to GC in the first 9 months of the pandemic were compared with patients who were operated before BP for GC in 9 months by performing a propensity score match analysis . Demographic characteristics of patients (age, gender), American Society of Anesthesiologist (ASA) scores, Charlson comorbidity index, admission symptoms (weight loss, abdominal pain, nausea-vomiting, malaise, melena, dysphagia), diagnostic methods (endoskopic, surgical), surgical characteristics (type, duration, emergency or elective), whether they received neoadjuvant therapy, tumor-node-metastasis (TNM) stages, pathological tumor stages at the time of operation, time from symptom onset to diagnosis, time from diagnosis to operation, whether pre-operative thorax computed tomography (CT) was taken, post-operative complications, length of hospital stay, duration of ICU stay, blood product requirement in the operation, serum carcinoembryonic antigen (CEA), alpha feto protein (AFP), carbohydrate antigen 19-9 (CA 19-9), hemoglobin level, kidney function tests, liver function tests, glucose value and patient costs were compared.

TNM classification made by the International Union for Cancer Control (UICC) and the American Joint Cancer Committee (AJCC) was used as the staging system.

For our study, research approval was obtained from Turkish Ministry of Health and The study was approved by the institutional ethics committee.

Statistical analysis

IBM SPSS version 22.0 (IBM Corporation, Armonk, NY, USA) was used for data analysis in our study. The patients who were operated during AP were matched with the patients who were operated during BP with the propensity score match analysis. Continuous variables were expressed as mean±standard deviation or median (min-max), and categorical data were expressed as numbers and percentages. Normality analyzes of continuous variables were performed using the Kolmogorov-Smirnov goodness-of-fit test. Because the data did not fit into the normal distribution, AP and BP comparisons were made with the Wilcoxon Ordered Signs Test. Chi-square test was used to compare categorical data. Statistical significance level was considered as $p<0.05$.

Results

A total of 55 patients, 21 (38.2%) female and 34 (61.8%) male, with a mean age of 65.1±10.7 years and a mean ASA score of 2.5±0.5 were included in the study. Twenty-eight (50.9%) of them were operated on during BP and 27 (49.1%) were operated on AP. The median Charlson comorbidity index was 2 [1-4] and all patients had at least one comorbidity; 24 (43.6%) patients had at least 2 or more comorbidities. The most common comorbidities were hypertension with 32.7% and diabetes mellitus with 14.5%. Hypertension (48.1% vs 17.9%; p=0.017) and coronary artery disease (22.2% vs 3.6%; p=0.045) were more common in patients in AP group. The most common symptoms at presentation were weight loss with 72.7%, abdominal pain with 67.3%, nausea and vomiting with 38.2% and melena with 10.9%. Three (5.5%) patients presented with dysphagia. In BP group, abdominal pain (89.3% vs 44.4%; p=0.010), nausea-vomiting (57.1% vs 18.5%; p=0.005) and weight loss (89.3% vs. 55%), 6; p=0.005) was more frequent. There was no difference in terms melena and other symptoms (p>0.05). There was no difference between the BP group and AP group in terms of age, gender, ASA, and comorbidities (p>0.005) (Table 1).

The time from symptom onset to diagnosis was statistically significantly longer in the AP group (87.5±78.2 vs 175.9±71.2 days; p<0.005). Out of 98.1% of patients were diagnosed endoscopically; 90.9% of them were operated under elective conditions. A total of 15 (27.3%) patients received neoadjuvant therapy. The number of patients who received neoadjuvant treatment was significantly higher in AP group (44.4% vs 10.7%; p=0.015). Laparoscopic GC surgery is rarely performed in our center in AP. Almost all of the patients were operated with conventional surgery (92.9% vs 100%; p=0.368). There was no difference between BP and AP for diagnosis method and operation planning . The hospitalization duration of the all study group was 11.4±4.7 days; length of stay in the ICU was 4.7±2.0 days; the median total cost was 11,244.0 TL (Turkish Lira) [9,443-15,202 TL]; there was no difference between the groups (p>0.05) (Table 1).

Table 1. Comparison of the general characteristics o participants between the study groups

Features	All Study Group (N=55,%)	Before Pandemic Group (N=28,%)	After Pandemic Group (N=27,%)	p
Age (years) (Mean±SD)	65.1±10.7	65.5±9.4	64.8±12.2	0.816*
Gender		0.458		
Female	21 (38.2)	10 (35.7)	11 (40.7)	>0.05**
Male	34 (61.8)	18 (64.3)	16 (59.3)	>0.05**
ASA (Mean±SD)	2.5±0.5	2.5±0.8	2.6±0.6	0.544**
Charlson comorbidity index (median)[25-75]	2 [1-4]	2 [2-4]	2 [1-4]	0.257**
Comorbodities				
Hypertension	18 (32.7)	5 (17.9)	13 (48.1)	0.017**
Diabetes mellitus	8 (14.5)	6 (21.4)	2 (7.4)	0.137**
Arrhythmia	3 (5.5)	0 (0)	3 (11.1)	0.111**
Coronary artery disease	7 (12.7)	1 (3.6)	6 (22.2)	0.045**
Chronic obstructive pulmonary disease	1 (1.8)	0 (0)	1 (3.7)	0.491**
Presenting Symptoms				
Abdominal Pain	37 (67.3)	25 (89.3)	12 (44.4)	0.010**
Nausea-Vomiting	21 (38.2)	16 (57.1)	5 (18.5)	0.005**
Weight Loss	40 (72.7)	25 (89.3)	15 (55.6)	0.005**
Weakness	16 (29.1)	6 (21.4)	10 (37.0)	0.164**
Melena	6 (10.9)	5 (17.9)	1 (16.7)	0.105**
Time From Symptom Onset To Diagnosis (days) (Mean±SD)		87.5±78.2	175.9±71.2	<0.005**
Diagnostic Method	0.368**			
Endoscopical	54 (98.1)	27 (96.4)	27 (100)	-
Surgical	1 (1.8)	1 (3.6)	0 (0)	-
Surgery Plan	0.187**			
Urgent	5 (9.1)	4 (14.3)	1 (3.7)	>0.05**
Elective	50 (90.9)	24 (85.7)	26 (96.3)	>0.05**
Neoadjuvant Therapy	5 (27.3)	3 (10.7)	12 (44.4)	0.015**
Type Of Surgery				
Open Surgery	53 (96.4)	26 (92.9)	27 (100)	>0.05**
Laparoscopic Surgery	2 (3.6)	2 (7.1)	0 (0)	>0.05**
Duration Of Hospitalization İn Intensive Care (days) (Mean±SD)	4.7±2.0	5.5±2.4	3.8±0.6	0.507*
Total Length Of Hospitalization (days) (Mean±SD)	11.4±4.7	12.7±2.3	10.0±0.5	0.263*
Total Cost (TL)[Median 25-75 Percentil]	11,244 [9,443-15,220]	17,056.75±3.493.21	11,795.71±556.683	0.437*

SD:Standart deviaiton, ASA: American Society of Anesthesiologists, TL:Turkish Lira
*T test, **Chi-square test

The time from neoadjuvant therapy to operation was similar (57.3±34.8 vs 62.8±55.5 days; p=0.441). Considering the surgery performed, total gastrectomy (TG) and D2 lymph node dissection (LND) were performed in 40 (72.7%) patients. Distal gastrectomy and D2 LND were performed in one (1.8%) patient. Combined organ resection (splenectomy, colon resection, cholecystectomy, etc.) was performed at a higher rate in AP group (44.4% vs 25.0%; p=0.019). The operation times of the two groups were similar (211.9±13.7 vs 177.8±13.8 min; p=0.085). A total of 10 (18.2%) patients required blood product replacement during the operation. There was no difference in terms of blood product requirement in BP and AP groups (p=0.389). Considering the pathological TNM stages, the number of stage 3B patients was higher in AP group (33.3% vs. 7.1%; p=0.04). Pathological N3 was higher in AP group (40.7% vs 23.1%; p=0.031). Post-operative complications were encountered in a total of 19 (34.5%) patients. Of these, 2 (3.6%) bleeding, 8 (14.5%) post-operative respiratory failure, 2 (3.6%) pulmonary embolism, 4 (7.3%) wound infection, and 3 of them (5.5%) were anastomotic leakage. There was no difference in terms of post-operative complications in of BP and AP groups (p>0.05) (Table 2).

Table 2. Compaison of the Operative Characteristics of the Participans Between te Study Groups			
Features	Before Pandemic Group (N=28,%)	After Pandemic Group (N=27,%)	p
Time to operation after neoadjuvant therapy (days) (Mean±SD)	57.3±34.8	62.8±55.5	0.441*
Surgery performed			
TG+D2 LND	21 (75.0)	19 (70.4)	0.467**
Distal gastrectomy+D2 LND	1 (3.6)	0 (0)	0.509**
TG+D2 LND+Cholecystectomy	2 (7.1)	1 (3.7)	0.514**
TG+D2 LND+Segmentary colon resection	1 (3.6)	1 (3.7)	0.745**
TG+ D2 LND+Splenectomy	3 (10.7)	2 (7.4)	0.518**
TG+D2 LND+Splenectomy+Cholecystectomy	0 (0)	1 (3.7)	0.491**
TG+ D2 LND+Liver metastatectomy	0 (0)	2 (7.4)	0.111**
TG+ D2 LND+Metastatectomy+Cholecytectomy	0 (0)	1 (3.7)	0.491**
Combined organ resection	7 (25.0)	12 (44.4)	0.019**
Operation time (minutes) (Mean±SD)	211.9±13.7	177.8±13.8	0.085*
Blood product requirement	6 (21.4)	4 (14.8)	0.389**
Pathological TNM Stage			
Stage 1A	3 (10.7)	6 (22.2)	>0.05**
Stage 1B	0 (0)	1 (3.7)	>0.05**
Stage 2A	3 (10.7)	3 (11.1)	>0.05**
Stage 2B	3 (10.7)	2 (7.4)	>0.05**
Stage 3A	8 (28.6)	4 (14.8)	>0.05**
Stage 3B	2 (7.1)	9 (33.3)	0.034**
Stage 3C	5 (17.9)	0 (0)	>0.05**
Stage 4A	4 (14.3)	2 (7.4)	>0.05**
Pathological Stages			
T Stage			
1A	2 (7.1)	1 (3.7)	0.514**
1B	1 (3.6)	0 (0)	0.509**
2	2 (7.1)	3 (11.1)	0.482**
3A	5 (17.9)	6 (22.2)	0.473**
3B	5 (17.9)	4 (14.8)	0.524**
4A	12 (42.9)	13 (48.1)	0.451**
N Stage			
N0	7 (25)	7 (25.9)	0.591**
N1	6 (21.4)	5 (18.5)	0.527**
N3	9 (23.1)	11 (40.7)	0.031**
M Stage			
MA	1 (3.6)	4 (14.8)	0.164**
Post-operative Complications			
Bleeding	1 (3.6)	1 (3.7)	0.745**
Respiratory failure/pneumonia	4 (14.3)	4 (14.8)	0.626**
Pulmonary embolism	1 (3.6)	1 (3.7)	0.745**
Wound infection	2 (7.1)	2 (7.4)	0.681**
Anastomotic Leakage	2 (7.1)	1(3.7)	0.514**
SD: Standard deviation, TG: Total gastrectomy, LND: Lymph node dissection, T: Tumor, N: Node, M: Metastasis *T test **Chi-square test			

In the pre-operative period, thorax CT was performed in 44 (80%) patients. The majority of them were in AP group. Three (5.5%) patients were reoperated. The reason for the operation was anastomotic leakage in 1 (1.8%) patient, deep wound infection in 1 (1.8%) patient, and bleeding in 1 (1.8%) patient.

When the laboratory findings and tumor markers of the patients were evaluated, no difference was found between the two groups in the period of BP and AP (p>0.05) (Table 3).

Table 3. Comparison of Laboratory Findings of the Participants Between the Study Groups

Features	Before Pandemic Group (N=28,%)	After Pandemic Group (N=27,%)	p
Hg (gr/dl)*	11.5±2.9	11.9±2.3	0.285***
Creatinine (mg/dl)*	0.9±0.3	0.8±0.2	0.364***
Glucose (mg/dl)*	106.0±22.2	105.5±29.9	0.364***
AST (U/L)**	17 [9-102]	16 [8-187]	0.731***
ALT (U/L)**	13.5 [6-97]	17.8 [6-111]	0.395***
CEA (µg/L)*	8.5±15.4	9.6±17.7	0.364***
AFP (ng/ml)*	3.6±3.0	3.3±1.9	0.459***
CA 19-9 (U/ml)**	11.4 [0.8-545.5]	11.1 [1-1584]	0.286***

*Mean±standard deviation; **Median [25-75 percentil], AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, CEA: Carcinoembryonic antigen, AFP: Alpha feto protein, CA 19-9: Cancer antigen 19-9
****Mann Whitney U Testi

In the postoperative period, repetitive COVID-19 real-time polymerase chain reaction (RT-PCR) was performed on upper respiratory tract samples from six patients with suspected COVID-19. No positive results were obtained.

Discussion

In our study, the COVID-19 pandemic did not make any difference on GC surgery on the diagnostic methods, operation types, surgical complications, length of hospital and ICU stay, and cost. However, patients who were operated in AP period were more symptomatic. More patients were referred to neoadjuvant therapy during the pandemic. In addition, the number of patients operated for TNM stage 3B GC and combined organ resection was higher in AP period.

The diagnosis of GC is mostly made by gastroscopy (endoscopy). The number of GC screenings has decreased during the COVID-19 pandemic. In 2020, the number of gastroscopies in Italy decreased by 53.6% compared to 2019, and by 57% in the Netherlands [4, 5] . There is a linear model relationship between the number of endoscopies performed and diagnosed gastric cancers. In the case of a 20% reduction in endoscopy, the average number of GC diagnoses per week was reduced by 54.1% [6]. This shows that there has been a decrease in the diagnosis of GC owing to the pandemic. Another study showed that hospital admissions decreased during the pandemic and patients wanted to receive health services such as video interviews[7]. As shown in our study, the COVID-19 pandemic caused a prolongation of the time from symptom onset to diagnosis and more symptomatic hospital admissions. The reason for the high number of advanced stage patients in AP group may be the delay in diagnosis. In the study of Li et al . [8] , the pandemic; showed that, it caused delay in admission of symptomatic patients to the hospital and a prolongation of the time from diagnosis to surgery.

Patients with locally advanced GC may be initially referred for neoadjuvant chemotherapy. Four weeks after the end of neoadjuvant treatment, patients were evaluated for suitability for surgery. Studies on neoadjuvant chemotherapy for gastric cancer demonstrated that a waiting period of more than 6 weeks before surgery can improve the rate of complete response, with no effect on prognosis [9] . This seems to have led to a tendency to neoadjuvant therapy as an alternative treatment option during the pandemic. In one study, treatment was delayed in 12% of patients with gastric cancer, and the treatment modality was changed to chemotherapy or immunotherapy in 20% of patients [7]. In our study, the number of patients who received neoadjuvant therapy was significantly higher in the AP group. This can be attributed to the avoidance of postoperative complications due to the COVID-19 pandemic, interrupting elective surgeries, or seeking alternative treatment to surgery..

In one study, it was concluded that by taking the necessary precautions, strict cancer treatment can be performed without delay, as stated in the usual guidelines, and this has no effect on mortality [10]. In our study, no positive

diagnostic test for COVID-19 was detected in any patient with suspected COVID-19 during the AP period. These results support the continuation of cancer treatment without disruption. Similar to our study Gocayev et al. [11] found that there were no significant differences in the duration of hospitalization, postoperative complications, and blood product requirements for BP and AP. In the study of Li et al. [8] they found that the postoperative hospital stay was longer and the total hospitalization cost increased in the AP period. However, in our study, no difference was observed between the two groups in terms of length of hospital stay and cost.

Conclusion

As a result, in our study, the time from symptom onset to diagnosis was prolonged in patients with gastric cancer during the pandemic period. This may have caused the patients to be more symptomatic at the time of presentation and disease progression while waiting for surgery. We think that this may be due to reasons such as PCR tests, decreased endoscopic procedures, and the reluctance of patients to visit the hospital during the pandemic. To avoid complications related to the COVID-19 pandemic after surgical treatment, patients may have been referred to neoadjuvant therapy as an alternative.

Ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board of University of Health Sciences, Dışkapı Yıldırım Beyazıt Training and Research Hospital (reference no.: 106/23) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards

Conflict of Interest

The authors have no conflict of interest to declare.

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