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Cost of care associated with utilization of telehealth in clinical trials

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ABSTRACT

Objective: Due to COVID-19 pandemic restrictions, telehealth was incorporated into standard oncologic care and clinical trial operations. We sought to analyze whether telehealth changed cost of care compared to traditional clinical trial operations.

Methods: We conducted a retrospective cohort study of gynecologic oncology patients enrolled in therapeutic clinical trials at a National Cancer Institute designated center, comparing the cost of cancer care on trial pre-TELEhealth (9/30/2019 to 3/15/2020) versus during TELEhealth (3/16/2020 to 8/20/2020). Inclusion required trial participation during both study periods, ≥1 telehealth visit, and identifiable billing records. The analysis was from a healthcare sector perspective. Cost per patient per month on trial was calculated for scheduled (per protocol) and unscheduled (non-protocol) encounters using 2020 national Medicare reimbursement rates, not institution-specific prices. Pairwise t-tests between pre-TELE and TELE periods were performed.

Results: Twenty-eight patients were included in the study. The majority of patients (93 %) had ovarian cancer. One patient (4 %) had uterine and 1 (4 %) had concurrent ovarian/uterine cancer. Most patients had advanced-stage disease at diagnosis (93 %). Mean cost per patient per month was similar in pre-TELE and TELE periods ($3797 vs. $4720, $p = 0.064$). There were no cost differences among scheduled or unscheduled encounters, office or ED visits, admissions, outpatient procedures, nor those billed to study sponsors or patient's insurer.

Conclusions: Incorporating telehealth in gynecologic cancer clinical trials during the COVID-19 pandemic did not increase cost of care and may be a mechanism for decentralizing clinical trials, reducing barriers to trial participation, and improving the value of cancer care.

1. Introduction

The COVID-19 pandemic led to the widespread uptake and integration of telehealth into clinical practice. Although telehealth, the use of communications technology to deliver health care and other health-related services (which may consist of video or audio-only visits), existed before the pandemic, the Centers for Medicare and Medicaid Services (CMS) and private insurers had narrowly restricted its use to a subset of facilities and patients in rural areas. However, on March 6, 2020, under a waiver of the Social Security Act, CMS broadened coverage for telehealth throughout the public health emergency (PHE), and private insurers followed suit (Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19. Baltimore:, 2023). Telehealth utilization skyrocketed—Medicare fee-for-service beneficiary telehealth visits increased 62-fold, from 860,000 in 2019 to 53 million in 2020. Telehealth visits decreased in 2021 to 37 million but remained over 40 times

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higher than in 2020 (Samson et al., 2023). Although the PHE ended on May 11, 2023, the Consolidated Appropriations Act of 2023 preserved many of the waiver's telehealth flexibilities through December 2024 (Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19. Baltimore:, 2023).

Telehealth in cancer care has been recognized for its capacity to reduce geographic and financial barriers to care. These benefits are particularly salient in gynecologic cancer, as half of U.S. counties lack access to a gynecologic oncologist (Ackroyd et al., 2021). In addition to improving care access, telehealth has been shown to maintain patient and clinician satisfaction, improve quality of life, and increase patient sense of independence (Sirintrapun and Lopez, 2018; Wong et al., 2022; Zimmerman et al., 2020). The National Comprehensive Center Network (NCCN) maintains that the best management for a patient with cancer is within a clinical trial, and telehealth and decentralized clinical trial operations offer the opportunity to increase access for patients who may otherwise be unable or unwilling to participate in clinical trials. Decentralized, remote trial operations may streamline care, reduce administrative burden, and decrease the need for patients to present in person for trial visits, medication receipt, and laboratory or imaging testing. Many clinical trials shifted to remote operations during the pandemic, and these changes were seen positively by patients, clinicians, and study staff (Wong et al., 2022). Despite the widespread implementation of telehealth in clinical trials, little is known about the financial impact of these changes. Given this, we sought to study whether incorporating telehealth into gynecologic cancer clinical trials would increase the cost of care for healthcare system payers, including patient insurance and study sponsors.

2. Methods

We conducted a retrospective cost identification study from the healthcare sector perspective to temporally compare the healthcare utilization of patients enrolled in gynecologic oncology clinical trials during the pre-telehealth period versus the telehealth period.

2.1. Inclusion criteria

Patients undergoing active treatment through therapeutic clinical trials at a single National Cancer Institute (NCI) Center during the pre-telehealth (pre-TELE) period (September 30, 2019, to March 15, 2020) and the telehealth (TELE) period (March 16 to August 20, 2020) were included. The study site enrolls approximately 50 patients in gynecologic cancer clinical trials annually. The study periods were chosen because they allowed the creation of two comparator cohorts: 1) patients enrolled in clinical trials before the implementation of telehealth services versus 2) the same patients enrolled in clinical trials during the required utilization of telehealth services as mandated by hospital policy during the COVID-19 pandemic.

Inclusion criteria required that each patient be enrolled and actively receiving treatment during both pre-TELE and TELE periods, have at least one virtual visit with a clinical trial clinician (MD or NP) or research coordinator during TELE and have identifiable billing records. Telehealth visits comprised either video or audio-only calls with both clinicians and research staff (such as clinical trial coordinators). Video calls were more frequently held with clinicians and audio calls with research staff. During the COVID-19 pandemic, patients participating in these clinical trials also had the option to receive labwork or imaging at outside facilities closer to their residence. Patients participating in clinical trials with per os (PO) medications also received these medications by mail during this time. Patients on surgical-only or CAR-T trials were excluded. Patient data was included up to the time of disease progression, regimen completion, patient withdrawal, or end of the TELE period. We have previously reported on the safety and feasibility of remote trial operations with this dataset, showing that remote clinical trials were not associated with increased major protocol deviations, emergency department or hospital admissions, or severe adverse events (Andriani et al., 2023).

Of note, patients in this study were required to have met the clinical trial eligibility criteria of their parent trials, which included predominantly NRG consortia trials. These eligibility criteria required that patients have Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2, no severe laboratory abnormalities (such as hemoglobin ≤ 9 or absolute neutrophil count ≤ 1500), no severe cardiac disease (such as myocardial infarction or unstable angina within six months, class 3 or 4 heart failure), or severe renal or liver disease, among other criteria.

2.2. Data Acquisition

Healthcare sector costs incurred included treatment and cancer-related healthcare costs. Using the electronic medical record and billing records, we compiled an itemized list of all healthcare utilization, including outpatient visits, hospital admissions (and associated provider billing), procedures (including anesthesia), laboratory testing, imaging, and medications received by patients during the study periods. We excluded services unrelated to cancer care (for example, a scheduled knee replacement for osteoarthritis).

Utilization data were multiplied by national Medicare reimbursement rates (rather than institution-specific prices) to estimate the cost for every participant event recorded. We used 2020 Medicare national average pricing data from CMS to achieve standardized and generalizable data. Outpatient visits, outpatient procedures, inpatient provider services, laboratory tests, and imaging were priced using the national reimbursement value corresponding to each Current Procedural Terminology (CPT) code. Of note, there was no difference in reimbursement between telehealth and in-person visits in the 2020 Medicare pricing data. Hospital admissions were given a diagnosis-related group (DRG) and priced according to the associated reimbursement. Anesthesia was priced in 15-minute intervals using the 2020 base units and national conversion factor. Medications were priced at Medicare Part B's average sales price. For outpatient prescriptions (like investigational oral chemotherapy agents), we used national GoodRx pricing data (GoodRx n.d. https://www.goodrx.com/go/homepage-lander-sem-7c=homepage-lander-sem-7optly_audience=%7Bnextbestaction%7Dutm_campaign=, 2024). Investigational drugs without an existing National Drug Code (NDC) were not included in pricing data. The overall cost per encounter, per patient, and patient per month on trial were calculated for scheduled (per clinical trial protocol) and unscheduled (non-protocol) encounters. Costs were not discounted because the analysis time horizon was less than one year. We used institutional billing data to determine which payer (study sponsor or patient insurance) was billed for each service.

2.3. Statistical analysis

Unpaired t-tests were used to compare clinical encounter costs, while pairwise t-tests were used to compare per-person costs between pre-TELE and TELE periods and cost differences between payers in pre-TELE and TELE periods. We assumed the cost of a service to be $0 if a subject did not have a particular encounter type during the study. This allowed pairwise tests to be used for the entire sample within each type of encounter. Statistical analysis was performed with STATA v17 (College Station, TX). This study was reviewed and deemed exempt by the University of Pennsylvania institutional review board (IRB-844075).

3. Results

Twenty-eight patients in 10 clinical trials met inclusion criteria (Table 1). The median age was 63 years (interquartile range [IQR]: 59.5–71.5). The majority of patients were White (24, 86 %). The remainder were Black (2, 7 %), Asian (1, 4 %), or did not specify. Most patients were non-Hispanic (27, 96 %). The median distance between the home zip code and the study site was 30 miles (IQR, 20–52.6 miles).

At baseline, 8 (29 %) patients had obesity, 2 (7 %) had diabetes, 5 (18 %) had a cardiac history (including coronary artery disease, atrial fibrillation, heart failure, or myocardial infarction), 2 (6 %) had chronic obstructive pulmonary disease, and 16 (57 %) had essential hypertension. Twenty-six patients (93 %) had ovarian cancer, one (4 %) had uterine cancer, and one (4 %) had concurrent ovarian and uterine cancer. Most (n = 26, 89 %) had stage 3 or 4 disease, and nine (32 %) patients were being treated for recurrence. The median duration of trial enrollment during the pre-TELE and TELE periods were 5.3 months (IQR, 3.7–5.5 months) and 5.5 months (IQR, 3.9–5.5 months), respectively. Fifteen patients (54 %) were on combined intravenous (IV) and oral (PO) chemotherapy clinical trials, nine patients (32 %) were on PO-only chemotherapy trials, and four (14 %) were on IV-only chemotherapy trials. All trials were phase II or III. Clinical encounters per trial protocol included visits with clinicians, trial coordinators, transfusion or infusion visits, lab appointments, imaging, procedures such as biopsies, and hospital admissions. After the study period, 61 % of patients remained actively on trial. Eight patients (29 %) experienced disease progression and discontinued their trial chemotherapy regimens. Two patients (7 %) completed their trial regimens and continued to active follow-up, and one patient (4 %) withdrew due to discomfort with trial participation during the COVID-19 pandemic. During the TELE period, all visits that could feasibly be held virtually were conducted via telehealth. In contrast, in-person visits were not (such as infusion visits). All PO medications were shipped to patients during the TELE time period, and patients could receive bloodwork or imaging at local sites outside the trial health system.

Table 1
Demographics and Disease Characteristics of Gynecologic Oncology Patients Who Used Telehealth while Enrolled in Therapeutic Clinical Trials.

	N = 28
Median [IQR]	
Age, (year)	63 [59.5–71.5]
Distance from trial center (miles)	30.2 [20.0–52.6]
Duration of Enrollment (months)	
Pre-TELE	5.3 [3.7–5.5]
TELE	5.5 [3.9–5.5]
Number (%)	
Race	
Asian	1 (4)
Black	2 (7)
White	24 (86)
Not specified	1 (4)
Ethnicity	
Hispanic/Latino	1 (4)
Non-Hispanic	27 (96)
Primary Insurance	
Private	16 (57)
Medicare	10 (36)
Medicaid	2 (7)
Comorbidities[a]	
Obesity[b]	8 (29)
Diabetes mellitus	2 (7)
Cardiac[c]	5 (18)
Chronic obstructive pulmonary disease	2 (7)
Hypertension	16 (57)
Cancer Type	
Ovarian	26 (93)
Ovarian/Uterine	1 (3)
Uterine	1 (3)
Stage	
I	1 (4)
II	1 (4)
III	15 (54)
IV	11 (39)
Recurrent Cancer	9 (32)
Route of Trial Medication	
PO	9 (32)
IV	4 (14)
IV and PO	15 (54)
Status at end of study	
Actively on trial	17 (61)
Progression	8 (29)
Completed regimen	2 (7)
Withdrew	1 (4)

Pre-TELE period defined as the period prior to incorporation of telehealth into clinical trials (September 30, 2019, to March 15, 2020). TELE period defined as the period after incorporation of telehealth into clinical trials (March 16 to August 20, 2020).

[a] Baseline comorbidities prior to study start.

[b] Body mass index > 30.0.

[c] Defined as history of coronary artery disease, atrial fibrillation, heart failure, or myocardial infarction.

3.1. Mean costs per clinical encounter

The total cost of care was $463,527 for pre-TELE and $661,533 for TELE. There were 323 clinical encounters in the pre-TELE period and 356 in the TELE period. In the TELE period, 34 % of clinician visits and 87 % of trial coordinator visits were held via telehealth. Care utilization during pre-TELE and TELE periods is presented in Table 2, with 292 versus 321 scheduled and 31 versus 35 unscheduled encounters, respectively. Among these encounters, 5,271 services were billed, and each study period had two per-protocol hospital admissions for planned interval debulking surgeries. Three unscheduled hospital admissions occurred during TELE for indications including severe anemia and

Table 2
Costs of Cancer-Related Care by Period by Encounter Type.

	Pre-TELE	TELE	*P* value
All Encounters			
Number	323	356	
Total Cost	463,527.20	661,533.10	
Mean cost (SD)	1,435.07 (2,647.18)	1,858.24 (3,298.42)	0.067
Scheduled Encounters			
Number	292	321	
Mean cost (SD)	1,514.55 (2,736.05)	1,806.87 (3,225.79)	0.229
Office visits			
Number	290	319	
Mean cost (SD)	1,423.54 (2,514.65)	1,684.15 (2,781.49)	0.227
Inpatient admissions			
Number	2	2	
Mean cost (SD)	14,710.42 (524.20)	21,381.14 (9,922.10)	0.443
Unscheduled Encounters			
Number	31	35	
Mean Cost (SD)	686.42 (1,399.95)	2,329.37 (3,925.04)	0.031
Office visits			
Number	30	28	
Mean cost (SD)	696.36 (1,422.76)	1,072.43 (1,932.97)	0.400
Inpatient admissions			
Number	0	3	
Mean cost (SD)	0	11,694.32 (6,528.85)	NA
ED visits			
Number	1	2	
Mean cost (SD)	388.02 (0)	751.16 (136.56)	NA
Outpatient procedures			
Number	0	2	
Mean cost (SD)	0	4,540.44 (1,027.08)	NA

Costs are presented in US dollars. Pre-TELE period defined as the period prior to incorporation of telehealth into clinical trials (September 30, 2019, to March 15, 2020). TELE period defined as the period after incorporation of telehealth into clinical trials (March 16 to August 20, 2020). Statistical testing was conducted using two-sided unpaired *t*-test at a significance level of 0.05.

appendicitis. There were two unscheduled outpatient procedures (cystoscopies) during the TELE period. No unscheduled inpatient admissions or outpatient procedures occurred during the pre-TELE period. The average total cost per encounter was similar between the study periods ($1435 versus $1858, p = 0.067). There was no significant difference in the average total cost per scheduled encounter between the study periods (p = 0.229). However, the average total cost per unscheduled encounter during TELE was greater than that of pre-TELE ($2329 versus $686, p = 0.031), given the greater number of unscheduled admissions during the TELE period.

3.2. Monthly costs per patient

When comparing the average cost per patient per month on trial, costs were higher in the TELE period for all encounter types ($3797 pre-TELE versus $4720 TELE, p = 0.064). However, this difference did not reach statistical significance (Table 3). There remained no difference between pre-TELE and TELE when considering only scheduled encounters ($3628 versus $4146, p = 0.189) or unscheduled encounters ($169 versus $575, p = 0.08), nor in any individual clinical encounter category.

3.3. Costs by payer

The study sponsor was billed for the majority (roughly 70 %) of all services in both study periods (Table 4). In the pre-TELE period, $1286 per patient per month was billed to the patient's insurance, whereas $3196 was billed to the study sponsor. In the TELE period, $1509 per patient per month was billed to the patient's insurance, whereas $4281 was billed to the study sponsor (p = 0.609 for insurance, p = 0.381 for the study sponsor).

4. Discussion

This single institution retrospective cohort study investigated the cost of care from the healthcare perspective associated with telehealth and remote gynecologic oncology clinical trial operations during the COVID-19 pandemic by comparing costs pre-telehealth and after the implementation of telehealth. While limited to a small cohort at one institution, our findings suggest that telehealth and remote trial operations did not increase the cost of scheduled or unscheduled care during the pandemic for study sponsors and patient insurance.

The financial toxicity associated with cancer care in the US is a growing challenge. As cancer treatments become increasingly advanced and personalized, patients face considerable financial burdens due to their care. The estimated yearly medical expenditure due to gynecologic cancers in the US is $3.8 billion, and these costs are expected to increase with the rising prevalence of gynecologic malignancies (Yue et al., 2020). Though over 70 % of services related to clinical trials were billed to the study sponsor rather than the patient's insurance in our study, there are still significant direct medical costs not covered by the trials. Several indirect costs are borne out of cancer care and participation in clinical trials that are not captured in billing data—for example, time taken off work, transportation costs, childcare costs, and the financial burden on patient caregivers. Remote clinical trial operations offer patients the flexibility to decrease indirect costs (for example, by attending a virtual visit with a study coordinator or obtaining labs at a local site). Our data suggest that these benefits do not, in turn, increase the direct cost of clinical trials.

Though little data exists describing the cost implications of remote clinical trial operations, literature on overall cancer care suggests that incorporating telehealth is cost-effective and beneficial to patients. For example, a Canadian study analyzing the implementation of virtual care across a large cancer center in 2020 demonstrated nearly $3 million in cost savings to patients and high levels of patient and provider satisfaction (Berlin et al., 2021). An analysis of over 25,000 telehealth visits at one NCCN-designated cancer center estimated mean savings by patients of over $150 per visit in indirect costs alone (cost of travel and loss of productivity) (Patel et al., 2023). Our study, which was the first US-based study to measure direct cost differences with telehealth implementation during the pandemic, suggests no added cost to patient insurance or sponsors from incorporating telehealth into cancer clinical trials. Although not significant, costs did trend higher in the TELE period, possibly due to the three unscheduled hospital admissions. Two of these were due to anemia in the setting of malignancy, and the other was an episode of acute appendicitis, which would have been difficult to predict or avoid. Our overall low rate of ED visits and hospitalizations pre-TELE were likely facilitated by the presence of an outpatient evaluation center for cancer patients, and research coordinators and nurses who helped triage and manage medical needs of clinical trial

Table 3
Average Cost of Cancer-Related Care per Patient Month.

	Pre-TELE (N = 28)	TELE (N = 28)	*P* value
All encounters	3,796.61 (3,874.01)	4,720.35 (4,842.98)	0.064
Scheduled encounters	3,627.83 (3,649.63)	4,145.60 (4,512.77)	0.189
Office visits	3,365.66 (3,684.03)	3,867.44 (4,174.38)	0.104
Inpatient admissions	262.17 (1,004.89)	278.16 (1,078.92)	0.956
Unscheduled encounters	168.78 (396.87)	574.74 (1,145.72)	0.08
Office visits	166.26 (397.65)	209.30 (561.26)	0.692
Inpatient admissions	0 (0)	278.61 (942.49)	0.129
ED visits	2.52 (13.36)	9.77 (36.20)	0.337
Outpatient procedures	0 (0)	77.07 (407.80)	0.326

Costs are presented in US dollars. Data reported as mean (standard deviation). Statistical testing was conducted using two-sided pairwise *t*-test at a significance level of 0.05.

Table 4
Average Cost of Cancer-Related Care per Patient Month By Payer.

	Pre-TELE (N = 28)	TELE (N = 28)	*P* value
PATIENT INSURANCE			
All encounters	1,285.56 (1,328.67)	1,509.39 (1,882.25)	0.609
Scheduled encounters	1,116.78 (1,187.18)	934.64 (1,369.55)	0.597
Office visits	854.60 (559.77)	656.48 (475.50)	0.159
Inpatient admissions	3,670.41 (1,497.12)	3,894.27 (1,807.17)	0.905
Unscheduled encounters	363.53 (526.97)	1,462.98 (1,454.23)	0.019
Office visits	358.10 (530.44)	532.76 (813.00)	0.533
Inpatient admissions	–	2,600.32 (1,713.51)	–
ED visits	70.67 (.)	136.81 (24.87)	–
Outpatient procedures	–	2,157.89 (.)	–
SPONSOR			
All encounters	3,195.89 (3,801.53)	4,281.28 (4,238.33)	0.381
Scheduled encounters	3,195.89 (3,801.53)	4,281.28 (4,238.33)	0.381
Office visits	3,195.89 (3,801.53)	4,281.28 (4,238.33)	0.381
Inpatient admissions	–	–	–
Unscheduled encounters	–	–	–
Office visits	–	–	–
Inpatient admissions	–	–	–
ED visits	–	–	–
Outpatient procedures	–	–	–

Costs are presented in US dollars. Data reported as mean (standard deviation). Statistical testing was conducted using two-sided pairwise *t*-test at a significance level of 0.05.

participants. These mechanisms likely reduced unnecessary emergency department visits and hospitalizations and remained in operation during the pandemic.

This study has several limitations. This was a retrospective study with a small cohort of patients; larger studies are needed to confirm our findings. This study was conducted at a single NCI-designated cancer center, and our findings may not be generalizable to all clinical trial sites. We measured only the direct costs for clinical services associated with clinical trials and did not measure many of the other costs borne by participants (transportation, etc.) or sites (delivery of medications, opportunity cost for orchestrating remote testing). Given incomplete data, we could not include clinical encounters at outside institutions. Our study site is in a large urban center, and participants traveled a median of 30 miles for their care, which in our metropolitan area may have involved significant interstate travel. Though telehealth still leads to decreased time and indirect travel costs (such as city parking, tolls, or public transportation fees) in this setting, future work is needed to confirm these results in rural healthcare settings of even greater geographic expanse. Additionally, the patient population in this study was predominantly white (83 %) and with ovarian cancer (93 %), reflecting the demographics of our baseline patient population who were eligible for clinical trials that were active within our trials portfolio at the time of this study. Given the trial eligibility criteria, this study population (and other patients in these clinical trials across the country), may be "healthier" than the average gynecologic cancer patient. The findings therefore may not be fully generalizable to all patient populations. Finally, our TELE period comprised data from the first five months of the pandemic and may not be representative of current remote trial operations. Many institutions implemented strategies to prevent ED visits or hospitalization during the early months of the pandemic; these strategies may have led to lower healthcare utilization during the TELE period than may have otherwise occurred. Additionally, 2020 Medicare reimbursement for telehealth offered parity to in-person encounters, but after the PHE, telehealth reimbursement has varied by state and public and commercial payers. Further work is needed to verify our results on a larger scale and impute additional indirect cost savings by patients.

In conclusion, incorporating telehealth in gynecologic cancer clinical trials during the COVID-19 pandemic did not increase the cost of scheduled or unscheduled care from the healthcare perspective, including patient insurance and study sponsors. Telehealth is critical to decentralizing clinical trials, reducing barriers to trial participation, and improving the value of cancer care.

Presentation

An earlier version of this study was published as an electronic abstract for the 2023 American Society of Clinical Oncology Annual Meeting.

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CRediT authorship contribution statement

Emily Gleason: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Leslie Andriani:** Writing – review & editing, Methodology, Investigation, Data curation. **Elizabeth A. Tubridy:** Writing – review & editing, Data curation. **Destiny Uwawuike:** Data curation. **Simon Gunter:** Writing – review & editing, Data curation. **Nathanael C. Koelper:** Writing – review & editing, Methodology, Formal analysis. **Heidi S. Harvie:** Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Emily M. Ko:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Dr. Ko has institutional research support from Tesaro and Faeth and an investigator research award from Bristol-Myers Squibb and Ovarian Cancer Research Alliance-Glaxo Smith Kline. Mr. Gunter reports personal fees from Merck outside the submitted work].

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