International Journal of Medicine
pISSN 1468-3814 | eISSN 2667-7008
https://theinternationalmedicine.com/

Original Researcher Article *DOI: 10.61336/im/26-07-49*

Relationship Between Acute Toxicity and Treatment Completion Time in Cervical Cancer Patients Receiving Chemoradiotherapy.

Nahar S[1]*, Haque MS[2], Hossain MRZ[3], Anika AS[4], Dilshad T[5], Ahmed M[6].

[1]*Associate Professor, Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh.*

[2]*Assistant Professor, Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh.*

[3]*Assistant Professor, Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh.*

[4]*Junior Consultant, Labaid Cancer Hospital and Superspeciality Centre, Dhaka, Bangladesh.*

[5]*Medical Physicist, Bangladesh Medical University, Dhaka, Bangladesh.*

[6]*Undergraduate Student of Biotechnology, BRAC University, Dhaka, Bangladesh.*

Correspondence:
Nahar S.
Associate Professor, Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh.

Email:
shamsunnahar73@yahoo.com

Received: 16-05-2026
Revised: 06-06-2026
Accepted: 25-06-2026
Published: 07-07-2026

Abstract

Introduction: Cervical cancer is the fourth most common malignancy among women globally, with concurrent chemoradiotherapy (CCRT) representing the standard of care for locally advanced disease. Acute toxicities arising during CCRT are among the most clinically significant contributors to treatment delays and prolonged overall treatment time (OTT), which adversely affect oncological outcomes. The relationship between toxicity severity and treatment completion time remains incompletely characterized, particularly in resource-limited settings. ***Aim of the Study:*** To evaluate the relationship between acute toxicities and treatment completion time in cervical cancer patients receiving CCRT, and to identify independent predictors of delayed treatment completion. ***Methods:*** This prospective observational study was conducted at the Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh, over one year. Sixty histologically confirmed cervical cancer patients (FIGO stage IB2–IVA) receiving CCRT were enrolled. Acute toxicities were graded using CTCAE v5.0. Treatment completion within 56 days was the primary outcome. Statistical analyses included chi-square tests, independent t-tests, and multivariate logistic regression. ***Results:*** The mean OTT was 61.2 ± 8.7 days; 36.7% of patients exceeded the 56-day threshold. Grade ≥2 toxicities were significantly associated with delayed completion (63.6% vs. 21.1%; p=0.002). Grade ≥2 anemia (36.7%) and neutropenia (21.7%) were significantly associated with treatment interruption (p=0.001 and p=0.021, respectively). On multivariate analysis, Grade ≥2 toxicity (OR 4.25; p=0.005), treatment interruption (OR 5.16; p=0.002), advanced FIGO stage (OR 3.42; p=0.017), and baseline anemia (OR 2.88; p=0.031) were independent predictors of delayed completion. ***Conclusion:*** Acute toxicity severity, baseline anemia, advanced disease stage, and treatment interruption are significant independent determinants of delayed CCRT completion. Proactive toxicity management, pre-treatment anemia correction, and early brachytherapy scheduling are essential to optimize treatment adherence and improve outcomes in cervical cancer patients.

Keywords: Cervical cancer; Concurrent chemoradiotherapy; Acute toxicity; Overall treatment time; Treatment completion; Brachytherapy; Anemia; Neutropenia; Bangladesh.

INTRODUCTION

Cervical cancer remains one of the most significant public health challenges worldwide, particularly in low- and middle-income countries (LMICs). According to the GLOBOCAN 2022 database, an estimated 662,301 new cases and 348,874 deaths from cervical cancer occurred globally in 2022, making it the fourth most common cancer and the fourth leading cause of cancer-related mortality among women worldwide.1 Strikingly, approximately 94% of these deaths occur in LMICs, where limited access to screening, vaccination, and timely treatment perpetuates a disproportionate burden of disease.2

In South Asia, the disease continues to cause substantial morbidity and mortality; in Bangladesh specifically, cervical cancer is among the most frequently diagnosed female cancers, with limited population-based screening infrastructure and late-stage presentation being persistent barriers to improved outcomes.3,4 The standard of care for locally advanced cervical cancer (FIGO stages IB2–IVA) is concurrent chemoradiotherapy (CCRT), comprising external beam radiotherapy (EBRT), concurrent platinum-based chemotherapy predominantly weekly cisplatin and intracavitary brachytherapy.5 The incorporation of cisplatin with pelvic radiation was established as the standard treatment following the National Cancer

Institute (NCI) alert in 1999, based on five landmark randomized controlled trials demonstrating superior overall survival and disease-free survival compared to radiotherapy alone.6 Subsequent meta-analyses and real-world studies have consistently confirmed a 6% absolute improvement in five-year survival with cisplatin-based CCRT.7 A critical determinant of treatment efficacy is the overall treatment time (OTT).

The American Brachytherapy Society (ABS) guidelines recommend completing the entire course of CCRT, including brachytherapy, within 56 days (8 weeks). Prolongation beyond this threshold is associated with tumor cell repopulation during treatment breaks, which significantly reduces local control and survival.8 A nationwide Taiwanese cohort study by Lin et al. (2017) encompassing 2,594 patients demonstrated that prolonged OTT was an independent predictor of poor cancer-specific survival (hazard ratio 1.33; $p<0.001$) and overall survival (hazard ratio 1.15; $p=0.05$).9 Despite this well-established evidence, real-world data consistently reveal that fewer than 50% of patients complete CCRT within the recommended timeframe, even in high-resource settings.10 Acute toxicities arising during CCRT are among the most common and clinically impactful causes of treatment delay and interruption. These toxicities encompass both hematologic manifestations—including anemia, neutropenia, and thrombocytopenia—and non-hematologic effects such as radiation dermatitis, nausea, vomiting, diarrhea, and cystitis.

The pelvic bone marrow, which contains a substantial proportion of the body's hematopoietically active tissue, is highly sensitive to combined-modality treatment, rendering hematologic suppression a particularly prevalent and consequential toxicity.11 Grade ≥2 hematologic toxicities have been reported to increase chemotherapy delay rates significantly, as demonstrated by Zou et al. (2021), who reported that grade 3–4 neutropenia led to delayed chemotherapy cycles in a substantial proportion of patients receiving cisplatin-based CCRT.12 Similarly, Holmqvist et al. (2022) showed that severe nausea and vomiting during CCRT were associated with dose modifications of both radiotherapy and chemotherapy, thereby extending OTT.13

While the prognostic implications of treatment prolongation are well-documented, the direct relationship between the spectrum of acute toxicities and treatment completion time particularly in the context of resource-limited settings such as Bangladesh remains incompletely characterized. Most existing studies originate from high-income countries or specialized cancer centers, and may not fully reflect the clinical realities faced in settings where advanced disease predominates, baseline anemia is prevalent, and supportive care resources are constrained. Understanding the specific toxicity profiles and their influence on OTT in this population is therefore essential for developing targeted, context-appropriate interventions. This study aimed to evaluate the relationship between acute toxicities and treatment completion time in cervical cancer patients receiving CCRT, to identify modifiable predictors of treatment delay that could inform quality improvement initiatives.

MATERIALS AND METHODS

This prospective observational study was conducted over one year at the Department of Clinical Oncology, Bangladesh Medical University, Dhaka, Bangladesh and included 60 patients with histologically confirmed cervical cancer scheduled to receive concurrent chemoradiotherapy (CCRT). Eligible patients were aged ≥18 years, had FIGO stage IB2–IVA cervical carcinoma, adequate baseline hematological and renal function (hemoglobin ≥8 g/dL, absolute neutrophil count ≥1,500/μL, platelet count ≥100,000/μL, serum creatinine ≤1.5 mg/dL), and an Eastern Cooperative Oncology Group (ECOG) performance status of 0–3.

Patients with prior pelvic radiotherapy, active autoimmune disease, or refusal to provide informed consent were excluded. All patients received standard pelvic external beam radiotherapy (EBRT) to a total dose of 45–50.4 Gy in 25–28 fractions using a linear accelerator with three-dimensional conformal radiotherapy or intensity-modulated radiotherapy techniques. Concurrent chemotherapy consisted of weekly intravenous cisplatin 40 mg/m², while carboplatin AUC 2 was administered in cisplatin-intolerant patients during EBRT. Following EBRT, high-dose-rate (HDR) intracavitary brachytherapy was delivered to a total dose of 24–30 Gy in 4–5 fractions. The target overall treatment time (OTT), defined as the interval from the first day of EBRT to the final brachytherapy session, was maintained at ≤56 days according to American Brachytherapy Society guidelines. Baseline demographic and clinical data were collected using a structured questionnaire, and patients were evaluated weekly during treatment and at each brachytherapy visit.

Acute toxicities were prospectively graded using the Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v5.0). Weekly monitoring included complete blood count and serum creatinine assessment, while treatment interruptions, chemotherapy delays, and dose modifications were documented prospectively. The primary outcome was treatment completion time, with delayed completion defined as OTT >56 days. Secondary outcomes included the occurrence and severity of acute toxicities, chemotherapy delay, treatment interruption, and their association with treatment completion time. Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY). Categorical variables were expressed as frequencies and percentages, whereas continuous variables were presented as mean ± standard deviation (SD).

Associations between acute toxicity grade and treatment completion time were assessed using the chi-square test, while mean treatment duration between subgroups was compared using the independent samples t-test. Multivariate binary logistic regression analysis was performed to identify independent predictors of delayed treatment completion, with results reported as adjusted odds ratios (ORs) and 95% confidence intervals (CIs). A p-value of <0.05 was considered statistically significant. Ethical approval was obtained from the Institutional Review Board, and written informed consent was obtained from all participants prior to enrollment.

RESULTS

Table 1: Socio-Demographic Characteristics (n=60)

Variables	Frequency (n)	Percentage (%)
Age (years)		
<40	10	16.7
40–49	22	36.7
50–59	18	30.0
≥60	10	16.7
Marital status		
Married	54	90.0
Unmarried	2	3.3
Widow	4	6.7
Residence		
Urban	24	40.0
Rural	36	60.0
Educational status		
No formal education	18	30.0
Primary	20	33.3
Secondary	15	25.0
Higher secondary & above	7	11.7
Smoking history		
Yes	8	13.3
No	52	86.7

This table describes the socio-demographic profile of the study participants. Most patients were aged 40–49 years (36.7%), followed by 50–59 years (30.0%). The majority were married (90.0%) and from rural areas (60.0%). Regarding education, 33.3% had primary education while 30.0% had no formal education. Only 13.3% of patients had a history of smoking.

Table 2: Clinical Characteristics of Patients with Cervical Cancer (n=60)

Variables	Frequency (n)	Percentage (%)
Histopathological type		
Squamous cell carcinoma	52	86.7
Adenocarcinoma	6	10.0
Others	2	3.3
FIGO stage		
Stage I	5	8.3
Stage II	20	33.3
Stage III	28	46.7
Stage IV	7	11.7
ECOG performance status		
0	12	20.0
1	30	50.0
2	14	23.3
≥3	4	6.7
Baseline hemoglobin (g/dL)	10.4 ± 1.5	
Baseline serum creatinine (mg/dL)	0.9 ± 0.2	

This table presents the clinical profile of the patients. Squamous cell carcinoma was the predominant histopathological type (86.7%). Most patients presented with FIGO stage III disease (46.7%). Half of the patients had ECOG performance status 1 (50.0%). The mean baseline hemoglobin level was 10.4 ± 1.5 g/dL and the mean serum creatinine level was 0.9 ± 0.2 mg/dL.

Table 3: Treatment Characteristics (n=60)

Variables	Frequency (n)	Percentage (%)
Concurrent chemotherapy drug		
Cisplatin	55	91.7
Carboplatin	5	8.3
Number of chemotherapy cycles		
<5 cycles	18	30.0
≥5 cycles	42	70.0
Brachytherapy received		
Yes	56	93.3
No	4	6.7
Chemotherapy delay		
Yes	20	33.3
No	40	66.7
Overall treatment duration (days)	61.2 ± 8.7	

This table summarizes treatment-related variables. Most patients received concurrent Cisplatin chemotherapy (91.7%), and 70.0% completed ≥5 chemotherapy cycles. Brachytherapy was administered to 93.3% of patients. Chemotherapy delay occurred in 33.3% of cases. The mean overall treatment duration was 61.2 ± 8.7 days.

Table 4: Distribution of Acute Toxicities (CTCAE v5.0, n=60)

Toxicities	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anemia	18 (30.0)	20 (33.3)	15 (25.0)	6 (10.0)	1 (1.7)
Neutropenia	35 (58.3)	12 (20.0)	8 (13.3)	4 (6.7)	1 (1.7)
Thrombocytopenia	42 (70.0)	10 (16.7)	5 (8.3)	2 (3.3)	1 (1.7)
Nausea/Vomiting	12 (20.0)	24 (40.0)	18 (30.0)	5 (8.3)	1 (1.7)
Diarrhea	25 (41.7)	18 (30.0)	12 (20.0)	4 (6.7)	1 (1.7)
Cystitis	38 (63.3)	12 (20.0)	7 (11.7)	2 (3.3)	1 (1.7)
Radiation dermatitis	20 (33.3)	22 (36.7)	13 (21.7)	4 (6.7)	1 (1.7)

This table demonstrates the frequency and severity of acute toxicities during chemoradiotherapy. Mild to moderate anemia and nausea/vomiting were the most common toxicities. Grade 3 and 4 toxicities were comparatively less frequent. Radiation dermatitis, diarrhea, cystitis, neutropenia, and thrombocytopenia were also observed with varying severity grades.

Table 5: Treatment Completion and Interruptions (n=60)

Variables	Frequency (n)	Percentage (%)
Treatment completed within planned time	38	63.3
Delayed treatment completion (>56 d)	22	36.7
Treatment interruption	18	30.0
No interruption	42	70.0

This table shows treatment completion status, interruption rates, and causes of delayed treatment. Overall, 63.3% of patients completed treatment within the planned duration, whereas 36.7% experienced delayed completion (>56 days). Treatment interruption occurred in 30.0% of patients.

Table 6: Acute Toxicity vs Treatment Completion Time (n=60)

Acute Toxicity Grade	Completed ≤56 d n (%)	Delayed >56 d n (%)	p-value
Grade 0–1	30 (78.9)	8 (21.1)	0.002
Grade ≥2	8 (36.4)	14 (63.6)	

This table evaluates the relationship between acute toxicity severity and treatment completion time. Patients with Grade 0–1 toxicities were more likely to complete treatment within 56 days (78.9%), whereas patients with Grade ≥2 toxicities had significantly higher delayed completion rates (63.6%). The association was statistically significant (p=0.002).

Table 7: Hematologic Toxicity vs Treatment Interruption (n=60)

Hematologic Toxicity (grade ≥2)	Interrupted n (%)	No interruption n (%)	p-value
Anemia	12 (66.7)	6 (33.3)	0.001
Neutropenia	7 (53.8)	6 (46.2)	0.021
Thrombocytopenia	4 (50.0)	4 (50.0)	0.084

This table assesses the association between hematologic toxicities and treatment interruption. Significant associations were found between anemia and treatment interruption (p=0.001), as well as neutropenia and treatment interruption (p=0.021). Thrombocytopenia showed no statistically significant association (p=0.084).

Table 8: Factors Associated with Treatment Duration (n=60)

Variables	Mean duration (days) ± SD	p- value
Age <50 yrs	58.4 ± 6.1	0.041
Age ≥50 yrs	63.8 ± 8.4	
FIGO stage I–II	57.9 ± 5.8	0.003
FIGO stage III–IV	65.1 ± 8.9	
Hb ≥10 g/dL	58.2 ± 6.0	0.001
Hb <10 g/dL	66.0 ± 8.5	
Any grade ≥2 toxicity	67.4 ± 7.2	<0.001

This table compares mean treatment duration according to different patient and disease factors. Older age (≥50 years), advanced FIGO stage (III–IV), baseline hemoglobin <10 g/dL, and Grade ≥2 toxicities were associated with significantly prolonged treatment duration.

Table 9: Multivariate Logistic Regression for Delayed Completion (>56 d)

Variables	Adjusted OR	95% CI	p-value
Grade ≥2 toxicity	4.25	1.52–11.84	0.005
Baseline anemia	2.88	1.10–7.53	0.031
Advanced stage (III–IV)	3.42	1.25–9.31	0.017
Treatment interruption	5.16	1.81–14.70	0.002

This table presents the independent predictors of delayed treatment completion. Grade ≥2 toxicity (Adjusted OR=4.25), baseline anemia (Adjusted OR=2.88), advanced disease stage (Adjusted OR=3.42), and treatment interruption (Adjusted OR=5.16) were all significantly associated with delayed treatment completion.

DISCUSSION

This study investigated the relationship between acute toxicities and treatment completion time in 60 cervical cancer patients receiving concurrent chemoradiotherapy (CCRT). The findings reveal several important patterns that align with, and in some respects extend, the evidence reported in recent literature spanning 2015–2026. In the present study, squamous cell carcinoma constituted the predominant histopathological type (86.7%), with the majority of patients presenting at FIGO stage III (46.7%). These epidemiological characteristics are consistent with global patterns reported in resource-limited settings. Locally advanced disease (stage III–IV) was a significant independent predictor of delayed treatment completion in our multivariate analysis (Adjusted OR=3.42; 95% CI: 1.25–9.31; p=0.017). This corroborates the nationwide Taiwanese cohort study by Lin et al. (2017), which analyzed 2,594 patients and demonstrated that advanced FIGO stage was among the most significant prognostic factors for poor cancer-specific survival and prolonged overall treatment time (OTT). That study further showed that patients completing CCRT within 56 days had significantly better five-year overall survival compared to those exceeding this threshold (p=0.002), firmly establishing the 56-day benchmark as the standard of care.9. Our study found that 36.7% of patients experienced delayed treatment completion beyond 56 days, with treatment interruption occurring in 30.0% of cases. These rates are notably higher than the 34% guideline-concordant completion reported by Valakh and Coopey (2019) in a single-center US retrospective study of 104 cervical cancer patients, where guideline-concordant completion was achieved in only one-third of cases, highlighting that treatment prolongation is a universal challenge regardless of healthcare setting.10 In a complementary study by Zaki et al. (2016), acute genitourinary (p=0.0007) and gastrointestinal toxicities (p=0.0002) were significantly associated with protracted treatment beyond 56 days—findings that closely mirror our results, where Grade ≥2 toxicity was the strongest independent predictor of delayed completion (Adjusted OR=4.25; p=0.005).14

Regarding hematologic toxicities, anemia was identified as both a common acute toxicity (Grade ≥2 in 36.7% of patients) and an independent predictor of delayed treatment completion (Adjusted OR=2.88; p=0.031) in the present study. This is consistent with findings from Shi et al. (2022), who reported that among 121 cervical cancer patients receiving CCRT, grade 3–4 anemia was significantly associated with reduced overall survival (hazard ratio 4.1; p=0.014).16 The mean baseline hemoglobin in our cohort was 10.4 ± 1.5 g/dL, and patients with hemoglobin below 10 g/dL had a significantly longer mean treatment duration (66.0 vs. 58.2 days; p=0.001), underscoring the clinical importance of pre-treatment anemia correction in this patient population. Neutropenia was found to be significantly associated with treatment interruption in our study (p=0.021), occurring as Grade ≥2 in 21.7% of patients. This aligns with data from Yang et al. (2023), who studied 112 early-stage high-risk cervical cancer patients and reported grade 2 or higher neutropenia in 20.5% of cases, with

neutropenia negatively correlated with radiotherapy treatment length ($r = -0.368$; $p=0.009$).11 Importantly, their study also noted that the duration of radiotherapy was an independent determinant of hematologic toxicity severity, creating a bidirectional relationship between treatment prolongation and bone marrow suppression. This bidirectionality is clinically significant and reinforces findings from Zou et al. (2021), who demonstrated that grade 3–4 neutropenia caused chemotherapy delay in a substantial proportion of patients receiving cisplatin-based CCRT, and that prophylactic use of PEG-rhG-CSF significantly reduced both neutropenia incidence and chemotherapy delay rates.12 Thrombocytopenia in our study showed no statistically significant association with treatment interruption ($p=0.084$), a finding also reported by Yang et al. (2023), where thrombocytopenia had a lower incidence and less influence on treatment continuity compared to other hematologic parameters.11

Nausea and vomiting, observed in Grade ≥2 severity in 40% of our patients, were among the most prevalent non-hematologic toxicities. This is consistent with a prospective study by Holmqvist et al. (2022) investigating 93 cervical cancer patients treated from 2013–2019, which showed that older patients (≥52 years) experienced significantly higher nausea and vomiting frequencies and higher grade ≥3 toxicities ($p<0.001$), and that Grade ≥3 nausea/vomiting was associated with dose modifications of both radiotherapy ($p=0.020$) and chemotherapy ($p=0.030$).13 In our cohort, older age (≥50 years) was similarly associated with longer mean treatment duration (63.8 ± 8.4 vs. 58.4 ± 6.1 days; $p=0.041$). A 2024 systematic review in Cureus further corroborated that gastrointestinal adverse effects including diarrhea, nausea, and vomiting are universal components of CCRT toxicity profiles and are consistently implicated in treatment modifications across patient populations.20. Treatment interruption, which occurred in 30.0% of our patients, was the most powerful independent predictor of delayed completion in multivariate analysis (Adjusted OR=5.16; 95% CI: 1.81–14.70; $p=0.002$). This finding is consistent with evidence from a prospective study from Northeast India (Baruah et al., 2022), which specifically noted that concurrent chemoradiotherapy-induced hematological toxicities are a major driver of therapy prolongation in similar low-resource settings where advanced-stage disease predominates.18 Their study reported grade 2 hematological toxicities in 77% of patients, with grade 3 in 15%, paralleling the spectrum observed in our cohort. In a broader context, the phase III randomized trial evaluating nedaplatin versus cisplatin (He et al., 2022) demonstrated that severe hematologic toxicities—particularly grade 3–4 neutropenia (19.4% vs. 13%) and thrombocytopenia—were significantly higher in the nedaplatin arm, reinforcing that cisplatin, used in 91.7% of our patients, remains the preferred agent for minimizing extreme hematologic events while maintaining treatment continuity.19 In summary, the present study confirms that Grade ≥2 acute toxicity, baseline anemia, advanced disease stage, and treatment interruption are independent determinants of delayed CCRT completion in cervical cancer patients, consistent with evidence from multiple recent international studies. The 56-day threshold remains a clinically and oncologically meaningful benchmark. These findings emphasize the need for proactive toxicity management strategies, including pre-treatment anemia correction, prophylactic hematopoietic support, and early brachytherapy scheduling, to optimize treatment adherence and ultimately improve outcomes in this vulnerable patient population.

Limitations of the Study:

This study is limited by its single-center design, small sample size of 60 patients, short one-year duration, absence of a control group, and lack of long-term follow-up data on disease control and survival outcomes, which may restrict the generalizability of the findings.

CONCLUSION

This study demonstrates that acute toxicity severity, particularly Grade ≥2 hematologic and non-hematologic toxicities, baseline anemia, advanced disease stage, and treatment interruption are significant independent determinants of delayed CCRT completion in cervical cancer patients. The 56-day overall treatment time benchmark is achievable in the majority of patients but remains challenged by toxicity-driven interruptions, especially in resource-limited settings where advanced-stage disease and baseline anemia predominate. Proactive toxicity surveillance, timely supportive care, and early brachytherapy scheduling are essential strategies to optimize treatment adherence and improve oncological outcomes in this vulnerable population.

RECOMMENDATIONS

Based on the findings of this study, several measures are recommended to improve treatment outcomes in cervical cancer patients receiving concurrent chemoradiotherapy. Pre-treatment correction of anemia, timely use of hematopoietic growth factor support in high-risk patients, and early scheduling of brachytherapy alongside EBRT may help reduce treatment interruptions and overall treatment prolongation. Regular weekly toxicity-directed multidisciplinary assessments should be implemented for early detection and management of adverse events. In addition, patient education, nutritional counseling, and adequate antiemetic support are essential, particularly for older patients who are more vulnerable to treatment-related complications. Finally, maintaining a prospective institutional registry of treatment delays and toxicity events may support continuous quality improvement and adherence to recommended treatment timelines.

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