

Is it possible to predict resectability in pancreatic cancers? A retrospective study in a tertiary center

*¿Es posible predecir la resecabilidad en los cánceres pancreáticos?
Un estudio retrospectivo en un centro terciario*

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Abstract

Objectives: Pre-operative radiological or laboratory evaluations can provide some insight into resectability in pancreatic ductal adenocarcinoma (PDAC). However, these methods still fall short, as patients may be deemed unresectable during perioperative exploration. Our study seeks to identify novel predictors that can accurately determine the resectability status of PDAC patients. **Methods:** Patients who underwent surgical exploration for potentially resectable PDAC were retrospectively analyzed and categorized into two groups: resectable and unresectable during exploration. Univariate and multivariate analyses were employed to predict resectability based on the identified predictors. **Results:** Out of the 120 patients who underwent surgical exploration, 30 (25%) were found to be unresectable during the surgical procedure. Multivariate analysis disclosed that tumor size ≥ 4 cm, carbohydrate antigen (CA) 19-9 > 500 U/mL, and lymphocyte count $\leq 1.55 \times 10^3/\mu\text{L}$ ($p = 0.013$, 0.014 , 0.031 , respectively) were associated with non-resectability. **Conclusions:** Tumor size, CA 19-9 levels, and lymphopenia have correlations with unresectability in PDAC patients. These factors can be valuable in preoperatively predicting the presence of an unresectable tumor.

Keywords: Pancreatic adenocarcinoma. Resectability. Predictive factor. Biological factors.

Resumen

Objetivo: Identificar nuevos predictores que puedan determinar de manera precisa el estado de resecabilidad de los pacientes con adenocarcinoma ductal pancreático (ADCP). **Métodos:** Se analizaron retrospectivamente los pacientes que se sometieron a exploración quirúrgica para ADCP potencialmente resecable y se categorizaron en dos grupos: resecables y no resecables durante la exploración. Se utilizaron análisis univariados y multivariados para predecir la resecabilidad basándose en los predictores identificados. **Resultados:** De los 120 pacientes que se sometieron a exploración quirúrgica, se encontró que 30 casos (25%) no eran resecables durante el procedimiento quirúrgico. El análisis multivariante reveló que un tamaño tumoral ≥ 4 cm, un nivel de CA 19-9 > 500 U/mL y un recuento de linfocitos $\leq 1.55 \times 10^3/\mu\text{L}$ ($p = 0.013$, $p = 0.014$ y $p = 0.031$, respectivamente) estaban asociados con no resecabilidad. **Conclusiones:** El tamaño del tumor, el nivel de CA 19-9 y la linfocitopenia tienen correlaciones con la irresecabilidad en pacientes con ADCP. Estos factores pueden ser valiosos para predecir preoperatoriamente la presencia de un tumor irresecable.

Palabras clave: Adenocarcinoma pancreático. Resecabilidad. Factor predictivo. Factores biológicos.

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Date of reception: 05-10-2023

Date of acceptance: 05-12-2023

DOI: 10.24875/CIRU.23000503

Cir Cir. 2026;94(5):549-555

Contents available at PubMed

www.cirugiaycirujanos.com

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Introduction

Among malignancies within the gastrointestinal system, pancreatic cancer exhibits notably high mortality rates. While surgery remains the most effective treatment approach, the 5-year survival rate stands at 10-25%.^{1,2} Determination of resectability primarily relies on pre-operative imaging techniques such as computed tomography (CT), magnetic resonance imaging, and endoscopic ultrasound, alongside biological factors. Numerous criteria, encompassing anatomical, biological, and conditional aspects, have been proposed to assess the resectability of pancreatic tumors.³ Anatomical parameters, including invasion of the superior mesenteric artery, hepatic artery, and aberrant hepatic artery, as well as unreconstructable involvement of the superior mesenteric vein and portal vein structures, were assessed as indications for unresectable conditions. Biological factors encompass lymphadenopathies that lack pathological confirmation on imaging or elevated levels of CA 19-9 exceeding 500 U/mL. Conditional variables were evaluated in conjunction with the patient's Eastern Cooperative Oncology Group (ECOG) score.⁴ Patients with elevated CA 19-9 levels, a sizable tumor on imaging, an indicative enlarged lymph node, substantial weight loss, and intense pain are categorized as high-risk individuals. Within this patient cohort, a more targeted diagnostic laparoscopy is recommended to assess resectability and ascertain the presence of micrometastasis.⁵

In pre-operative assessments, pancreatic ductal adenocarcinomas (PDACs) initially deemed operable based on contrast-enhanced CT scans were subsequently found to be unresectable in approximately half of the cases.⁶ While CT scans exhibit a high predictive value for identifying unresectable disease, their sensitivity in detecting resectable PDAC is limited. Consequently, alongside radiological imaging, biological factors are employed to evaluate the resectability of PDAC in patients.

The objective of our study is to identify novel radiological and biological variables, alongside the established criteria outlined in current guidelines, for determining the pre-operative resectability status of patients diagnosed with radiologically resectable PDAC.

Methods

Study design and patients

This research was conducted in accordance with the World Medical Association Declaration of Helsinki.

An opt-out informed consent protocol was used for this study. This consent procedure was reviewed and approved by the local ethical review board, approval number (2023/4702).

This retrospective study was conducted at a tertiary care center and included data from all patients who underwent the Whipple procedure at our facility between 2010 and 2022.

Inclusion criteria

- Tumors localized to the right side of the pancreas
- Anatomical structures appear amenable to surgical resection based on the assessment using pre-operative CT imaging
- Performance status ECOG 0 and ECOG 1
- Patients with final diagnosis of PDAC.

Exclusion criteria

- Neoadjuvant therapy
- Patients with distant metastasis detected on pre-operative CT.

During the course of the investigation, the resectability of the tumor was assessed by two experienced surgeons. Patients were categorized into resectable or unresectable groups based on the surgeons' judgment. Collected data included patient age; pre-operative laboratory measurements such as alanine aminotransferase, aspartate aminotransferase, γ -glutamyl transferase, total bilirubin, albumin, carbohydrate antigen (CA19-9), and carcinoembryonic antigen (CEA); lymphocyte count ($10^3/\mu\text{L}$); neutrophil count ($10^3/\mu\text{L}$); platelet count ($10^3/\mu\text{L}$); neutrophil-to-lymphocyte ratio (NLR); platelet-to-lymphocyte ratio (PLR); and tumor size observed on CT. The necessary data were obtained from the patients' database. Pre-operative imaging was reviewed by a specialized radiologist to assess anatomical resectability and identify the presence of distant metastases.

Statistical analysis

The sample size for this study was determined using power analysis with G-Power 3.1 software. A power ($1-\beta$) of 0.80 and a confidence level of 95% were considered, resulting in a calculated sample size of 29 participants per group. Therefore, a minimum total sample size of 58 participants was determined for

both groups. The normality of the distribution was assessed using the Shapiro-Wilk test. Non-parametric tests, specifically the Mann-Whitney U test, were employed as appropriate. Descriptive statistics, including median and interquartile range (IQR), were reported for the variables. The optimal cutoff point for tumor size, lymphocyte count, NLR, and PLR was determined using receiver operating characteristic (ROC) curve analysis. Categorical variables were analyzed using χ^2 analysis, and the results were presented as frequencies and percentages. Subsequently, a prospective selective multivariate logistic regression analysis was conducted to examine the variables that demonstrated statistical significance. The goodness of fit of the logistic regression model was assessed using the Hosmer-Lemeshow test. Statistical significance was defined as $p < 0.05$.

Results

Demographic and clinical characteristics

A retrospective analysis was conducted on the data of 159 patients who underwent laparotomy for right-side pancreatic mass in a study. Pathology results from 39 patients (24.53%) were excluded as they did not meet the criteria for PDAC. Among the remaining 120 patients included in the analysis, 30 (25.0%) were found to be unresectable during intraoperative exploration (Fig. 1). A detailed analysis of patient data is presented in tables 1 and 2. The median age (IQR) of the study population was 66 (59-73), with 84 (70.0%) being male. Moreover, the performance status of the patients who underwent surgery was categorized as ECOG0 in 39 individuals (67.5%) and ECOG 1 in 81 individuals (32.5%).

Predictive factors for unresectable and resectable on exploration

The group of patients with unresectable tumors displayed several distinct characteristics compared to the group with resectable tumors. First, the unresectable group consisted predominantly of elderly individuals, with a median age of 74 years, whereas the resectable group had a median age of 63 years ($p < 0.001$). Furthermore, the unresectable group exhibited significantly larger tumor sizes, with a median value of 4.65 cm, as opposed to 3.5 cm in the resectable group ($p < 0.001$).

Table 1. Demographic and clinical characteristics of included patients

Variables	Median (IQR)	Count (%)
Age	66 (59-73)	
Gender		
Female		36 (30.0)
Male		84 (70.0)
Performance status		
ECOG 0		81 (67.5)
ECOG 1		39 (32.5)
Resectability		
Unresectable		30 (25.0)
Resectable		90 (75.0)
Morbidity (CD)		
I-II		8 (6.7)
III-IV		97 (80.8)
		23 (19.2)

IQR: interquartile range; ECOG: Eastern Cooperative Oncology Group; CD: Clavien-Dindo classification.

In addition, patients belonging to the unresectable group demonstrated higher levels of specific biomarkers in comparison to the resectable group. Specifically, the unresectable group displayed elevated levels of CA 19-9 (375.95 vs. 47 U/mL, $p = 0.002$), CEA (5.48 vs. 2.5 ng/mL, $p < 0.001$), NLR (3.46 vs. 2.41, $p = 0.013$), and PLR (205.17 vs. 148.05, $p = 0.034$) in comparison to the resectable group. However, it is important to note that the lymphocyte count was significantly lower in the unresectable group (1.34 vs. $1.8 \times 10^3/\mu\text{L}$, $p < 0.001$) (Table 2).

The ROC curve analysis was performed to determine the optimal cutoff points for tumor size (≥ 4 cm), CA 19-9 (≥ 75 U/mL), CEA (≥ 6 ng/mL), lymphocyte count ($\leq 1.55 \times 10^3/\mu\text{L}$), NLR (≥ 3.2), and PLR (≥ 171). The analysis aimed to identify the threshold values at which these parameters could effectively discriminate between different groups. In addition, the specific value of CA 19-9 > 500 U/mL was also assessed and tested (Table 3).

In univariate regression analyses, several factors were found to be significantly associated with the resectability status of PDAC during surgery. These factors included older age ($p < 0.001$), larger tumor size ($p = 0.001$), elevated levels of CA 19-9 (> 500 U/mL; $p < 0.001$, ≥ 75 ng/mL; $p = 0.207$), elevated levels of CEA ($p < 0.001$), increased NLR ($p = 0.009$), higher PLR (PLR; $p = 0.012$), and lower lymphocyte count (< 0.001) (Table 4).

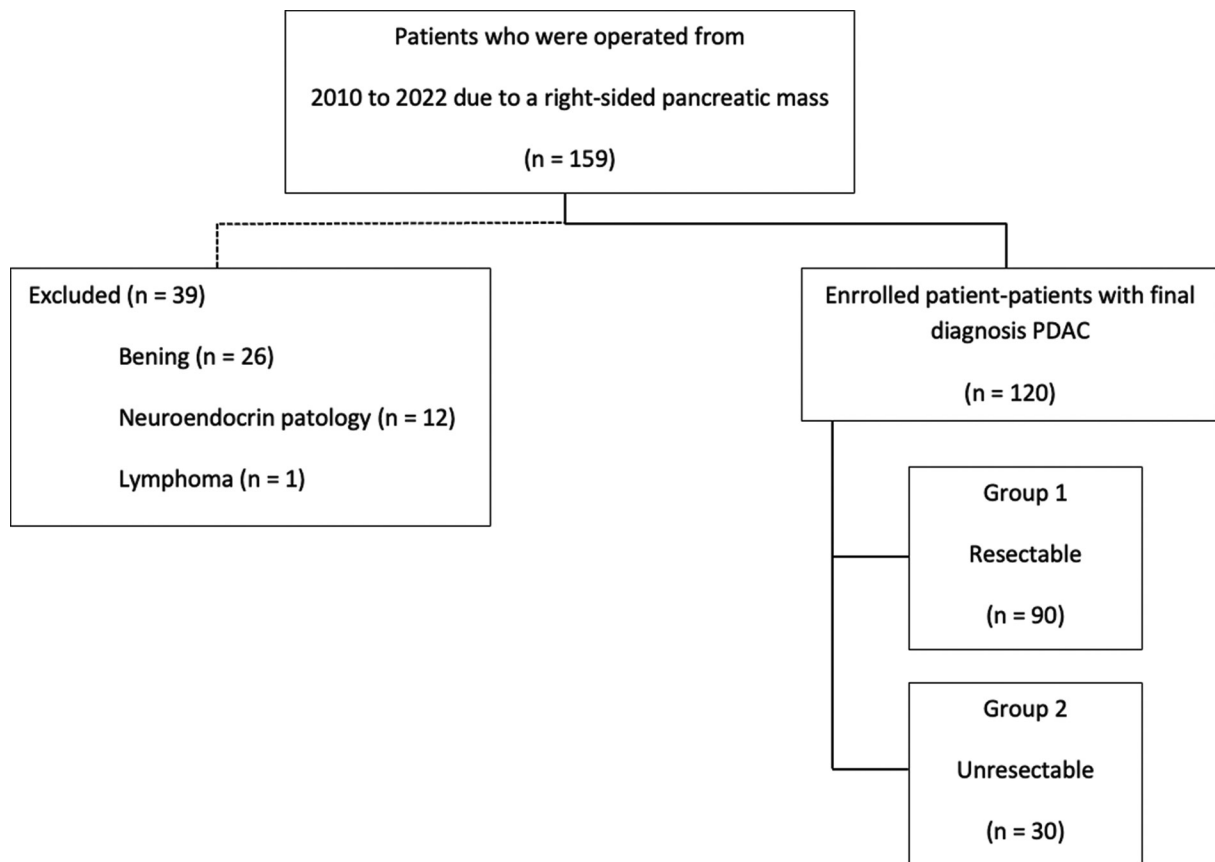


Figure 1. Patient flowchart

In the multivariate analysis, after adjusting for other variables, the following factors remained significantly associated with the unresectable group. These factors were tumor size ≥ 4 cm (odds ratio [OR] = 4.152; 95% confidence interval [CI] = 1.358-12.697; $p = 0.013$), CA 19-9 > 500 U/mL (OR = 9.929; 95% CI = 1.602-61.552; $p = 0.014$), and lymphocyte count $\leq 1.55 \times 10^3/\mu\text{L}$ (OR = 4.253; 95% CI = 1.142-15.838; $p = 0.031$) (Table 4).

Discussion

Currently, the evaluation of resectability in PDAC patients is based on the pre-operative criteria set by the International Association of Pancreatology (IAP).³ Treatment decisions for patients are made accordingly. However, there is a subset of patients with radiologically potentially resectable PDAC who do not receive curative treatment. One of the contributing factors is the limitations of imaging methods. Consequently, unnecessary laparotomy procedures are performed in cases where pancreatic resection is not

feasible, leading to significant morbidities. Moreover, this delays the initiation of chemotherapy regimens, resulting in reduced overall survival for patients.

Recent studies conducted on radiologically potentially resectable PDAC patients have revealed that several factors, including CA 19-9, CEA, CA 125, DUPAN-2, tumor size, weight loss, and tumor location (specifically left-sided tumors), can serve as predictive indicators of unresectability.⁷⁻¹⁰

In our study, we observed that tumor size, CA 19-9 levels, CEA levels, lymphocyte counts, NLR, and PLR exhibited statistically significant associations in univariate regression analyses. However, after adjusting for potential confounders, we found that tumor size ≥ 4 cm, CA 19-9 levels exceeding 500 U/mL, and lymphocyte counts $\leq 1.55 \times 10^3/\mu\text{L}$ emerged as independent risk factors for resectability.

CA 19-9 is extensively investigated as a tumor marker for the diagnosis and prognosis of pancreatic cancers. In our study, we determined a cutoff value of 75. In addition, we examined the recommended value of 500 U/mL by the IAP. An elevated CA 19-9 level of

Table 2. Univariate analysis of factors predicting unresectability

Variables	Resectability				p
	Unresectable		Resectable		
	Median (IQR)	Count (%)	Median (IQR)	Count (%)	
Age, year	74 (69-78)		63 (58-70)		<0.001
Gender					
Female		9 (30.0)		27 (30.0)	0.597
Male		21 (70.0)		63 (70.0)	
Performance status					
ECOG 0		18 (60.0)		63 (70.0)	0.311
ECOG 1		12 (40.0)		27 (30.0)	
Tumor size, cm	4.65 (4-5.5)		3.5 (2.9-4.5)		<0.001
CA 19-9, U/mL	375.95 (20-1016)		47 (1.6-282.1)		0.002
CEA, ng/mL	5.48 (3.10-8.62)		2.5 (1-4.2)		<0.001
Albumin, g/dL	3.2 (2.7-3.9)		3.3 (2.8-3.7)		0.932
AST, U/L	58 (23-135)		42.5 (21-87)		0.231
ALT, U/L	57.5 (25-212)		63 (28-122)		0.942
GGT, IU/L	117 (66-453)		178 (58-369)		0.894
Total Bilirubin, mg/dL	1.15 (0.61-9.32)		1.9 (0.9-6.4)		0.456
Lymphocyte, 10 ³ /uL	1.34 (0.94-1.71)		1.8 (1.5-2.3)		<0.001
Neutrophil, 10 ³ /uL	4.98 (3.76-5.45)		4.85 (3.6-6.5)		0.524
Platelet, 10 ³ /uL	250 (208-311)		290.5 (221-336)		0.083
NLR	3.46 (2.76-5.33)		2.41 (1.81-3.87)		0.013
PLR	205.17 (135-252.31)		148.05 (108-205.83)		0.034
Morbidity (CD)					
I-II		1 (3.3)		7 (7.8)	0.398
III-IV		25 (83.3)		72 (80)	
		5 (16.7)		18 (20)	0.688

p < 0.05 was considered statistically significant.

CA 19-9: carbohydrate antigen 19-9; CEA: carcinoembryonic antigen; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio; CD: Clavien-Dindo classification; ALT: alanine aminotransferase; AST: aspartate aminotransferase; GGT: γ -glutamyl transferase.

500 U/mL was found to increase the risk of the tumor being unresectable approximately tenfold. Van Manen et al.⁷ suggested a cutoff of 305 U/mL for CA19-9, which resulted in an OR of 2.58 (95% CI 1.30-5.14; p = 0.007). Zhang et al. reported that a CA 19-9 level exceeding 353.3 U/mL predicted non-resectability in pancreatic cancer patients who underwent laparotomy.¹¹ Conversely, the study by Benke et al. emphasized that CA 19-9 should not be solely relied upon as a safe marker for determining resectability in surgical decision-making.¹²

Our study's observed low cutoff value is likely attributed to the inclusion of exclusively right-sided

pancreatic tumors. This selection may have influenced the results, as left-sided pancreatic tumors exhibit a higher prevalence of distant metastasis and locally advanced stage upon diagnosis.¹³

It is widely recognized that pancreatic head adenocarcinomas often coincide with elevated bilirubin levels. Consequently, CA 19-9 measurements may not be suitable for assessing patients with jaundice. A correlated study demonstrated that a CA 19-9 value exceeding 178 U/mL can serve as a reliable indicator of unresectable disease in patients experiencing jaundice.¹⁴

Table 3. Validity of independent factors predicting unresectability

Variables	Cutoff	Sensitivity (%)	Specificity (%)	AUC	95% CI	p
Tumor size, cm	≥ 4	76.67	60.00	0.683	0.576-0.791	0.003
CA 19-9, U/mL	> 500	50.00	81.11	0.656	0.536-0.775	0.011
CA 19-9, U/mL	≥ 75	56.67	56.67	0.567	0.448-0.685	0.275
CEA, ng/mL	≥ 6	50.00	83.33	0.667	0.547-0.786	0.006
Lymphocyte, 10 ³ /uL	≤ 1.55	70.00	66.67	0.683	0.573-0.794	0.003
NLR	≥ 3.2	63.33	64.44	0.652	0.524-0.754	0.023
PLR	≥ 171	63.33	63.33	0.630	0.518-0.749	0.029

p < 0.05 was considered statistically significant.

CA 19-9: carbohydrate antigen 19-9; CEA: carcinoembryonic antigen; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio; AUC: area under the curve; CI: confidence interval.

Table 4. Univariate and multivariate logistic regression analysis results

Variables	Univariate logistic regression			Multivariate logistic regression		
	OR	95.0% CI	p	OR	95.0% CI	p
Tumor size ≥ 4 cm	4.929	1.915-12.684	0.001*	4.152	1.358-12.697	0.013
CA 19-9 > 500 U/mL	4.294	1.765-10.449	< 0.001*	9.929	1.602-61.552	0.014
CA 19-9 ≥ 75 U/mL	1.710	0.743-3.937	0.207	5.238	0.898-30.573	0.066
CEA ≥ 6 ng/mL	5.000	2.022-12.363	< 0.001*	2.130	0.713-6.367	0.176
Lymphocyte ≤ 1.55 10 ³ /uL	4.667	1.906-11.426	< 0.001*	4.253	1.142-15.838	0.031
NLR ≥ 3.2	3.131	1.326-7.390	0.009*	1.706	0.439-6.634	0.441
PLR ≥ 171	2.983	1.266-7.032	0.012*	1.485	0.357-6.180	0.587

p < 0.05 was considered statistically significant.

CA 19-9: carbohydrate antigen 19-9; CEA: carcinoembryonic antigen; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio; OR: odds ratio; CI: confidence interval.

The enlargement of pancreatic tumors, similar to other malignancies, has a notable impact on prognosis, overall survival, and the likelihood of resectability. A study conducted by Chiang et al. indicated that pancreatic adenocarcinomas with a tumor size exceeding 4.8 cm are more prone to being unresectable. The authors also emphasized the importance of evaluating clinical characteristics of the tumor in conjunction with radiological imaging.¹⁵ Another study reported a higher probability of unresectability in pancreatic adenocarcinomas with a tumor size of 3 cm or greater.⁸ In our study, we found that cases with a tumor size of 4 cm or larger had an approximately fourfold increase in unresectability. It is important to note that the distinguishing factor of our study was the standardized patient group consisting exclusively of right-sided pancreatic tumors.

Immunosuppression plays a significant role in the advancement of malignancies, including pancreatic cancer. Both lymphopenia and a high NLR serve as indicators of an unfavorable prognosis, indicating the presence of advanced-stage disease.¹⁶ A study further highlighted that an NLR exceeding 3.74 independently increases the risk in cases of unresectable PDAC.¹⁷ In our study, although NLR did not emerge as an independent risk factor, lymphopenia demonstrated predictive value for identifying unresectable PDAC.

Limitations of the study

A limitation of the study lies in the relatively small cohort of patients with unresectable conditions. By broadening the study population, we can effectively elucidate the risk factors associated with resectability

in a more definitive manner. Furthermore, this expansion will facilitate the development of nomograms, enabling accurate prognostic predictions and individualized treatment strategies.

Conclusions

In cases of radiologically assessable PDACs, the incorporation of variables such as CA19-9 > 500 U/mL, lymphocyte $\leq 1.55 \times 10^3/\mu\text{L}$, and tumor size ≥ 4 cm can enhance the precision of resectability assessment. This refined evaluation aids in minimizing unwarranted laparotomies. Moreover, it is prudent to contemplate exploratory intervention following neoadjuvant therapy when there is concurrent manifestation of all three specified prognostic indicators. This counsel is underpinned by the plausible prospect of encountering non-resectable pathologies during the course of diagnostic intra-abdominal scrutiny.

Funding

The authors declare that they have not received funding.

Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of human subjects and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality, informed consent, and ethical approval. The authors have obtained approval from the Ethics Committee for the analysis of routinely collected and anonymized clinical data; therefore, individual informed consent was not required. Relevant ethical recommendations have been followed.

Declaration on the use of artificial intelligence.

The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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