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The Association Between Medication Adherence and Drug-Related Problems (DRPs) with Clinical Outcomes of Diabetes Patients at Public Health Center in Salatiga

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ABSTRACT

Background: Diabetes mellitus (DM) is a disease whose clinical condition can be controlled. The clinical outcomes of DM patients are an important parameter for successful treatment and are influenced by many factors.

Objectives: This study aimed to analyze the relationship between medication compliance and drug-related problems (DRPs) with the clinical outcomes of diabetes patients at three Primary Health centers in Salatiga.

Methods: An observational study method was adopted with prospective data collection from the medical records and medication compliance observation of type 2 diabetes mellitus (T2DM) patients, in October 2023–April 2024. DRP analysis was based on categories Cipolle, 2012, and medication compliance was measured using the pill count method. Data analysis was conducted using the Spearman test to assess the correlation between medication adherence and HbA1c levels, as well as the occurrence of DRP.

Results: A total of 40 subjects participated in this study, with the largest gender being female (72.5%), and hypertension was the most common comorbid condition (55%). The highest compliance rate in patients was 40% and DRP events were detected in 107 cases. The difference in patient HbA1c levels at baseline and the 3rd month showed a significant difference, and 67.5% experienced an increase. Furthermore, there was a strong relationship between compliance and HbA1c achievement (sig = 0.003, r = 0.452), as well as between the incidence of DRP and HbA1c achievement (sig = 0.000, r = 0.644).

Conclusion: Compliance and DRPs influenced the HbA1c levels of T2DM patients in PROLANIS across three Public Health Centres in Salatiga.

Keywords: Compliance, Drug Treatment Problems, HbA1c

INTRODUCTION

Diabetes mellitus (DM) is the biggest global problem in the 21st century and a serious threat to world health.[1] This disease is an incurable but controllable long-term metabolic condition marked by high levels of fasting blood glucose levels >125 mg/dl or HbA1c >6.5%. Patients must adhere to treatment to facilitate the control of diabetes. Uncontrolled diabetes conditions, such as fasting blood sugar >130 mg/dl or HbA1c >7% over several years, can cause serious health problems to the heart, blood vessels, eyes, kidneys, and nerves.[2] The findings from the Basic Health Research (Riskesdas) carried out by the Indonesian Ministry of Health in 2018 indicated that the prevalence of chronic diseases, including diabetes mellitus (DM), in Indonesia stood at 10.9%. This figure marks an increase from the 6.9% reported in 2013. The incidence of DM, as diagnosed by healthcare professionals among individuals of all ages and those over 15 years in Central Java Province, surpasses the

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national average. Specifically, in Central Java, the rate of newly diagnosed diabetes cases is recorded at 13.4%. If left untreated, this condition can result in various complications, thereby escalating the burden on national health insurance systems and diminishing overall quality of life.[3]

DM requires long-term treatment, and the main problem in this context is low levels of patient compliance.[4] WHO reports that in most developed countries, the compliance rate for chronic disease patients undergoing long-term treatment is only 50%, which is lower in developing countries.[5] According to Rahmawati (2023), low and high levels of compliance are not affected by factors such as demographic characteristics, total number of treatments, and total frequency.[6] Factors that influence compliance with treatment include patient characteristics, socioeconomics, morbidity, treatment, and the health service system.[7] For diabetic patients on long-term medication, large doses, adverse side effects, and the perception that treatment does not cure the disease contribute to boredom and lead to non-compliance.[8] Furthermore, non-compliance with treatment leads to worse clinical outcomes and can cause damage to vital organs. Treatment failure will have a negative impact in the form of increasing the burden of costs individually and on health insurance providers.[9]

Patients who take medication regularly over a long period have several unmet needs. The need may be related to the indication, effectiveness, drug safety, or compliance. When patients' needs are not fulfilled immediately, it can cause undesirable impacts. Pharmacists in pharmaceutical services must assess whether patient needs related to drug are fulfilled and identify the occurrence of drug-related problems (DRPs).[10] These problems cause the failure of DM treatment, leading to poor clinical outcomes, decreased patient quality of life, and increased treatment costs. DRPs are influenced by the presence of comorbidities, use of various drug, significant drug interactions, poor medication compliance, uncontrolled blood pressure, type 2 diabetes, abuse of narcotics and dangerous drug, as well as low patient confidence in treatment being carried out. However, a previous study reported that continuous pharmaceutical services in healthcare facilities can reduce DRP's occurrence.[11] DRPs can significantly cause morbidity and mortality, as well as a huge increase in economic burden.[12] Pharmacists must identify, minimize, and prevent the occurrence of DRPs to reduce the incidence of morbidity, mortality, and the economic burden caused by DRPs. A previous study proved that pharmacist services were able to identify 61% of DRP events and subsequently resolve the problem. This procedure leads to an 83% improvement in patient clinical status and healthcare savings of $1,134,162.[10] Therefore, this study aimed to determine the prevalence of DRPs and medication compliance in type 2 diabetes mellitus (T2DM) patients at the public health center in Salatiga City, Central Java, from December 2023 to April 2024. This study is crucial due to the inadequate management of clinical parameters among DM patients enrolled in Prolanis at the Salatiga City Public Health Centre, and previous investigations have not addressed the specific question.

METHODS

A descriptive-analytical study was conducted using medical record data from T2DM patients participating in the Chronic Disease Management Program (PROLANIS) at three Community Health Centers in Salatiga City from October 2023 to April 2024. The study subjects were not given interventions or did not carry out other activities.

Study design

An observational study method was adopted with prospective data collection on medical records and observing medication compliance of patients who routinely take PROLANIS in three public health centers in the city of Salatiga for the period October 2023 – April 2023.

Population and samples

The study's population comprised all PROLANIS patients from three health centres in Salatiga City. The sample consisted of individuals from this population who satisfied the inclusion criteria, namely PROLANIS participants diagnosed primarily with DMT2, aged between 36 and 65 years, and with HbA1c levels ranging from 7% to 10%. Participants were required to engage in PROLANIS activities for three consecutive months and to be willing to report any remaining medication. Furthermore, there was a need to have comprehensive medical records that included personal information (age, gender, and comorbidities), medication details (name, dosage, frequency, and quantity received), as well as objective data such as HbA1c levels, blood pressure, and lipid profiles. A consecutive sampling method was used, leading to a total of 40 subjects who met the inclusion criteria. The number of respondents exceeded the minimum required sample size of 30 for statistical analysis.

Study instruments

The major instrument used in this study was a Case Report Form (CRF). The identity of patients included name, initials, medical record number, diagnosis of T2DM, age, gender, name of drug, amount received, interval of use, and remaining amount of drug, as well as data on HbA1c and lipid profile values included in the CRF.

Data collection

Study samples were collected using the purposive sampling method. The study was conducted at three public health centers in the city of Salatiga from October 2023 to April 2024.

Data Analysis

Univariate Analysis

This univariate analysis aimed to outline the features of each variable under investigation. The results included age, gender, and diagnosis, pattern of use of oral hypoglycemia drug, and those for comorbidities, and calculation of compliance to taking medication using the pill count method[13], analysis of the incidence of DRP based on Cipolle-Strand-Morley Criteria 2012[14], and calculation of the difference in HbA1c levels at baseline and 3rd month.

Bivariate Analysis

The relationship between the two variables under study was examined using bivariate analysis through the Spearman Rank test. Even though the Spearman statistical test was non-parametric, the data did not have to be normally distributed. The significance value in the Spearman test showed that there was a correlation between the two variables, while the correlation coefficient determined the strength.

Eligibility criteria

The sample comprised medical record data and observations of patient compliance that satisfied the inclusion criteria. The specified inclusion criteria were patients with comprehensive medical records that included identification (age, gender, and comorbid conditions), medication history (which includes name, dosage, frequency of administration, total amount received, and remaining quantity over one month), as well as objective data such as HbA1c levels and lipid profiles. This study excluded individuals who did not consistently engage in PROLANIS activities, healthcare professionals, and pregnant individuals.

RESULTS AND DISCUSSION

A total of 40 DM patients participated in PROLANIS at the Salatiga City Public Health Center, with 11 male respondents (27.5%) and 29 female respondents (72.5%). The results were consistent with the theory that sex and gender differences were associated with increased rates of T2DM and its complications. T2DM was more frequently diagnosed in patients with the most prominent risk factor, namely obesity, which was more common in women.[15,16] Other risk factors, such as psychosocial stress, also played a significant role for women diagnosed with diabetes. Psychosocial stress appeared to have a greater impact on women than men.[15–17] In women, psychosocial elements, including educational attainment, socioeconomic standing, employment status, and low income, were identified as key risk factors contributing to the onset of Type 2 Diabetes Mellitus (T2DM).[15,18,19] In comparison with men, women experience greater hormonal fluctuations and body changes due to reproductive factors. Menopausal conditions could increase the cardiometabolic risk profile in women. Therefore, women with type 2 diabetes showed a greater relative risk of cardiovascular disease (CVD) and death compared to men.[16] The incidence of cardiovascular complications and death was also higher in women with type 2 diabetes than in men [17]

Women in midlife often experience a rise in the ratio of fat to body weight, which was more pronounced than that of men, with a higher accumulation of visceral fat in the abdominal area.[20] The percentage of visceral fat in the body showed a significant correlation with hypertension (P=0.007), dyslipidemia, and type 2 diabetes (P=0.048).[21] Adiponectin was a type of adipokine that was produced and released in large quantities by adipose tissue. It was primarily recognised for its beneficial effects that included antidiabetic, anti-inflammatory, antiatherogenic, and cardioprotective properties.[22–24] Visceral body fat usually inhibited the action of adiponectin, which was then associated with the development of insulin resistance, eventually leading to T2DM.[21]

Table I. Demographic characteristics of respondents (n=40)

Characteristic	N (%)
Gender	
Male	11 (27.5)
Female	29 (72.5)
Age (year)	
36 – 45	1 (2.5)
46 – 55	11 (27.5)
56 – 65	28 (70.0)
Diagnostic	
T2DM + Hypertension	17 (42.5)
T2DM + Hypertension + Hyperlipidemia	13 (32.5)
T2DM	6 (15.0)
T2DM + Hyperlipidiemia	4 (10.0)
Number of medication	
2 Drug	5 (12.5)
3 Drug	11 (27.5)
4 Drug	13 (32.5)
5 Drug	6 (15.0)
6 Drug	4 (10.0)
7 Drug	1 (2.5)

A previous study reported an increase in the occurrence of multimorbidity, characterised by the simultaneous presence of multiple diseases in individuals suffering from Non-Communicable Diseases.[25] Currently, approximately one-third of adults across the globe experience multimorbidity, leading to a significant public health challenge internationally due to its effects on healthcare systems and the associated economic strain.[26] Comorbidity referred to the presence of multiple chronic conditions within an individual, often stemming from a shared disease index observed in DM. The result of this study showed that prevalent comorbidities among DM patients included hypertension and dyslipidemia. A study conducted on the DM population at King Abdulaziz University Hospital (KAUH) in Jeddah, Saudi Arabia, showed that the frequently encountered comorbidities were hypertension, ischaemic heart disease, and dyslipidemia.[27]

On average, each patient received 3.9 drug in this study. The majority received 4 types of medication, namely 32.5% of respondents. Patients received between 2 and 7 drug prescribed by doctors at the primary health center. There was a possibility that patients also consumed supplements and herbal medicines other than those prescribed by the doctor. Meanwhile, polypharmacy referred to the concurrent use of multiple medication. While there was no universally accepted definition, a comprehensive review of existing literature showed that polypharmacy was typically characterised by the regular administration of five or more drug, with definitions varying from two to eleven medication.[28] This included over-the-counter prescription medication and traditional and complementary medicines used by the patient.[29] Another systematic literature review defined polypharmacy using a minimum number ranging from 4 to 6 drugs/day.[30] Polypharmacy was often found in around two-thirds of the population of elderly people with diabetes.[30] Elderly individuals with diabetes who experienced polypharmacy may be at higher risk of several negative health-related outcomes, such as poor glycemic control[31] and hypoglycemic events[32,33], syncope[32], poor quality of life[34,35], the need for inpatient hospital care[32], and death[32,36]. Important issues related to polypharmacy in diabetes patients have also been proven to cause a decrease in patient compliance to consuming anti-diabetic drug, resulting in poor glycemic control and an increased risk of diabetes complications.[37]

The quantity of medication administered to patients aligned with their medical conditions and any accompanying comorbidities. Patients with Type 2 Diabetes Mellitus (T2DM) who presented with additional complex health issues necessitated a greater pharmacological intervention to manage their blood glucose levels and related complications. These objectives were achievable by increasing the number of medication, leading to lower rates of noncompliance.[38,39] Table 2 shows the treatment pattern of DM patients participating in PROLANIS at the Salatiga City Public Health Center. The types of drug used in the treatment of DM patients participating in

Prolanis were biguanides, sulfonylureas, and alpha-glucosidase inhibitors. This was because only these three classes of oral hypoglycemia drug were available through the BPJS Health referral program.

Table II. Treatment pattern (n=40)

Characteristic	Medication	N (%)
Diabetes mellitus treatment		
	Bigunaide	11 (27.5)
Monotherapy	Sulfonylureas	4 (10.0)
	Alpha-glucosidase inhibitor	1 (2.5)
2 Drug	Biguanide + Sulfonylurea	16 (40.0)
3 Drug	Biguanide + Sulfonilurea + Alpha-glucosidase inhibitor	8 (20.0)
Hyperlipidemia	Simvastatin	10 (25.0)
Antihypertension		
	Angiotensin Receptor Blocker (ARB)	8 (20.0)
Monotherapy	Amlodipine	5 (12.5)
	Spironolactone	1 (2.5)
2 Drug	ARB + Spironolakton	6
	Amlodipine + ARB	3
	Amlodipine + Bisoprolol	1
	Furosemide + Bisoprolol	1
	Spirinolakton + Captopril	1
3 Drug	Amlodipine + Candesartan + Spironolakton	3
Others		
Vitamins	B6	23 (57.5)
	B12	4 (10.0)

The diabetes medication frequently administered to PROLANIS patients at the Salatiga City Public Health Centre belongs to the biguanide class and is known as metformin. This medication is recognised as a first-line treatment option endorsed by the Indonesian Endocrinology Association for managing DM.[40] American Diabetes Association and the European Association for the Study of Diabetes[41] have endorsed metformin as the primary medication for managing T2DM since 2006. This recommendation is based on several factors, such as metformin is cost-effective, shows high effectiveness, is generally well tolerated, has mild adverse effects, poses a low risk of hypoglycaemia, and can be easily combined with all other oral hypoglycaemic agents. Furthermore, metformin contributes to a moderate reduction in body weight and may help lower the risk of cardiovascular complications and mortality.[42,43] The American Diabetes Association, alongside the European Association and numerous research studies, supports the utilisation of GLP-1 receptor agonists and SGLT2 inhibitors for patients with type 2 diabetes who either currently have or are at a considerable risk of cardiovascular disease (CVD) and chronic kidney disease (CKD).[44–48]

The result of this study showed that there was a significant increase in the average patient HbA1c (p-value = 0.001) after 3 months (Table III). A total of 27.5% of respondents experienced a decrease in HbA1c, showing the success of treatment. Similarly, 67.5% of respondents experienced an increase in HbA1c, and 5% of respondents had a constant HbA1c level for 3 months. The tendency for patients' HbA1c to increase could be caused by low compliance with treatment. In this study (Table VI), all respondents were identified as experiencing DRPs in the compliance category. Compliance with treatment greatly influenced the achievement of successful control of patient clinical outcomes.[13] The relatively high incidence of DRP could also be a cause of worsening clinical outcomes in DM patients.[49]

Table III. HbA1c level at baseline and after 3 months (n=40)

Baseline mean±SD	**3rd month** mean±SD	**p-value**
8.365 ± 0.8377	8.895 ± 1.3517	0.001*

Table IV. Pattern of change in HbA1c levels at baseline versus after 3 months (n=40)

	Pattern	**N (%)**
HbA1c Baseline vs HbA1c 3rd month	Decreased	11 (27.5)
	Increased	27 (67.5)
	Equal	2 (5)
	Total	40 (100)

The management of clinical outcomes for DM patients could be enhanced through various strategies, such as offering Diabetes Self-Management Education (DSME). This method was shown to considerably lower HbA1c and fasting blood glucose levels in individuals with T2DM at Primary Health Care facilities in Binjai City, North Sumatra, Indonesia.[50] DSME was designed to enhance the knowledge, skills, and competencies required for managing prediabetes and diabetes independently. The purpose of this method was to promote informed decision-making, self-management practices, effective problem-solving, and active engagement with the healthcare team, aiming to improve clinical outcomes, health, and quality of life.[51] Furthermore, the intervention of pharmacists for T2DM patients by carrying out counseling once a month and providing reminder SMS weekly was shown to significantly reduce HbA1c, Total Cholesterol, LDL-c, and Triglycerides. This intervention also significantly increased medication compliance in outpatients with T2DM.[52]

The result of this study showed that T2DM patients still have low compliance in taking medication, where only 40% were compliant and 60% of patients were non-compliant (Table IV). This result was consistent with the study conducted by Suprapti (2023) on outpatient T2DM patients at a hospital in Surabaya City, showing that 83.5% of patients were non-compliant with treatment.[53] A study at 3 public health centers in Bantul district showed that 57% of patients had low levels of compliance.[54] Another report at a diabetes care referral center in Crato, Ceará (Brazil), including 300 respondents, showed that 77.3% had a low level of compliance.[55] Non-compliance in patients with T2DM could lead to elevated blood glucose levels and HbA1c, thereby increasing the risk of both microvascular and macrovascular complications, including retinopathy, nephropathy, neuropathy, and various CVD.[56] Another study proved that 50% of T2DM patients were non-compliant with the antidiabetic drug prescribed treatment regimen. Socioeconomic status was found to influence patient compliance, where patients in the low category had low levels. [57]

Table V. Description of respondent compliance by pill count (n=40)

Pattern	**N (%)**
Compliance	16 (40)
Non-compliance	24 (60)

Measuring medication compliance using the pill count method was carried out by calculating the remaining medication of the patient after 30 days. The calculation was carried out by visiting the patient's home, because Prolanis activities were conducted every 28 days, different from the amount of medication given for use for 30 days. Non-compliance with treatment was a problem that often occurs and increased the cost for T2DM patients.[58] A research study conducted in the United States involving 237 participants found that the most commonly cited challenges included forgetting to take doses, the belief that brand-name medications are more effective than their generic counterparts, a lack of immediate perceived benefits, and a sense of monotony associated with the routine of taking diabetes medication.[59] A systematic literature study showed that several obstacles caused low T2DM patient compliance, including low patient knowledge about diabetes, lack of patient confidence in medicines, lack of awareness and negative attitudes towards the disease condition, lack of support from family or friends, local food culture, use of herbs, and the lack of environmental sensitivity of Health service providers. Therefore, health service providers need to strengthen DM treatment management and address the various factors influencing compliance .[54,60]

In Table VI, DRPs were identified in 107 cases, with each patient experiencing between one and four events. These included the need for additional drug treatment, such as 14 patients with LDL levels above 100 mg/dL who should have received statin treatment, and 10 patients requiring combined treatment because HbA1c levels had decreased but had not yet reached the target. Some patients did not receive statin treatment even though LDL was > 100 mg/dL. This was because BPJS Health provisions required that statin treatment could be given to T2DM patients with LDL levels > 130 mg/dL.[61] The next DRP event was ineffective medication, observed in patients with HbA1c levels above 9% that did not decrease after three months despite receiving oral hypoglycemic drug treatment. According to the management, 12 people should have been given insulin. The obstacle was patient reluctance to accept referral to a hospital, since insulin use at a public health center required a previous hospital referral and a prescription from an internal medicine specialist. Another DRP incident was drug side effects, where 3 patients reported experiencing gastrointestinal diseases after consuming metformin, such as heartburn and diarrhea. The highest incidence of DRP was in the non-compliance category, where 19 patients deliberately did not take medication or reduced the frequency of use, not adhering to the doctor's instructions. In this study, no DRP was found in drug categories “not showed”, “dose too low”, and “dose too high”.

Table VI. DRPs

DRPs category	Causes of DRPs	Description of DRPs	N
Unnecessary drug treatment			0
Need additional drug treatment	A medical condition requires the initiation of drug treatment (untreated condition).	LDL >100 mg/dL has not received treatment	14
	A medical condition requires additional pharmacotherapy to attain synergistic or additive effects (synergistic treatment).	HbA1c has decreased, but has not reached the target, other drug need to be combined	10
Ineffective drug	The drug is not the most effective for the medical condition, and a different drug is needed (a more effective drug is available.	HbA1c>9%, according to PERKENI management for T2DM with HbA1c>9% insulin treatment is recommended	12
	The medical condition is refractory to the drug product, and a different drug is needed.	Patients on drug monotherapy but with HbA1c>7.5% or patients who have received a combination of 3 drugs but with HbA1c>7.5%	28
Dosage too low			0
Adverse drug reaction	The drug product causes an undesirable reaction that is not dose-related.	The patient received metformin and experienced gastrointestinal discomfort, such as pain and diarrhea	3
Dosage too high			0
Non- compliance	The patient prefers not to take medication.	Patients decide not to take medication or reduce the frequency of use because they are worried they will experience other health problems due to consuming too many medication	19
	The patient forgets to take medication.	Patients forget to take medication due to age or busyness	21
		Total	107

A study at the Universitas Gadjah Mada Academic Hospital provided an overview of 38 DRP incidents, which included categories requiring additional drug treatment, wrong drug, and doses being at 26.3%, 55.2%, and 18.4%, respectively.[62] Another study of 36 T2DM patients showed that the incidence of DRP was 80.56% of the proportion of patients, which included the categories of unnecessary drug treatment (47.22%), too low drug dose (41.67%), requiring additional drug treatment (27.78%), drug dose was too high (13.89%), drug was

ineffective (22.22%), and the incidence of drug side effects (5.56%).[63] The incidence of DRP in various studies showed different patterns that could be influenced by study location, DRP determination instruments, and patient demographics. The presence of comorbidities (hypertension) increased the number of medication, and polypharmacy was a very high-risk factor associated with DRPs.[49] In this study, the condition of T2DM patients with accompanying hypertension was quite high. The incidence of DRP in T2DM patients was also high 55%, thereby increasing the DRP in general.

Table VII. Relationship between medication compliance and DRP with HbA1c levels

	sig (2-tailed)	Correlation coefficient
Compliance with HbA1c level	0.003*	0.452
DRP with HbA1c level	0.000*	0.644

Table VII showed that there was a strong relationship between compliance with taking medication and HbA1c levels (r= 0.452; sig= 0.003). Therefore, it was concluded that a high level of compliance produced good HbA1c levels. Treatment compliance was known to be a factor that influenced HbA1c levels. Several studies showed that high compliance was associated with lower HbA1c levels, regardless of the method for measuring compliance.[64–67] T2DM patient compliance with treatment was associated with increased HbA1c levels in most classes of oral hypoglycemia treatment.[68]

The result of this study proved that there was a strong relationship between the incidence of DRP and HbA1c levels (r= 0.644, sig= 0.000). In a study of 50 T2DM patients with neuropathy complications, it was proven that there was a relationship between DRPs with antidiabetic drug and the achievement of control of fasting blood sugar levels and postprandial blood sugar levels.[62] Another study conducted at an academic hospital in the city of Surakarta showed that there was a relationship between the incidence of DRP in T2DM patients with accompanying hypertension and blood sugar control during.[69] Analysts experienced limitations because many DM patients are Prolanis participants who did not routinely visit the doctor to refill the medication, leading to difficulty in obtaining data on a larger population. Based on the results, the recommendation was to implement pharmacy services by pharmacists to reduce the incidence of DRPs and improve control of patient clinical outcomes.

CONCLUSION

In conclusion, compliance and DRP influence the clinical outcome of T2DM patients participating in PROLANIS at the Public Health Center in Salatiga City. Noncompliant patients and the high incidence of DRP cause the HbA1c to be uncontrolled. The role of pharmacists is needed in pharmaceutical care for DM patients to increase medication compliance and the achievement of controlled HbA1c conditions, as well as reduce DRP.

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STATEMENT OF ETHICS

This study complies with ethical guidelines and has been approved by the Medical and Health Research Ethics Committee, Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, under reference number KE/FK/1595/EC/2022, December 2022, and KE/FK/2049/EC/2023, December 2023.

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