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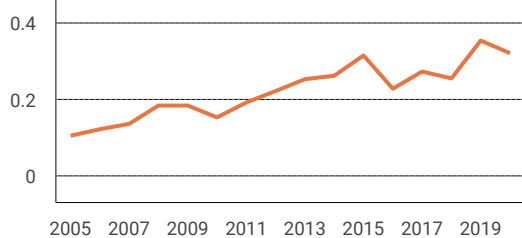
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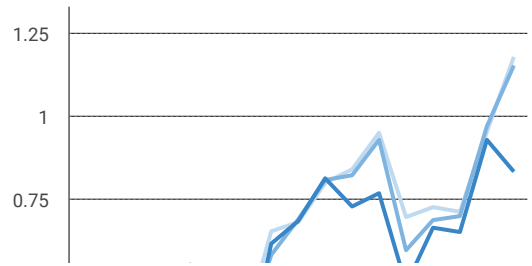
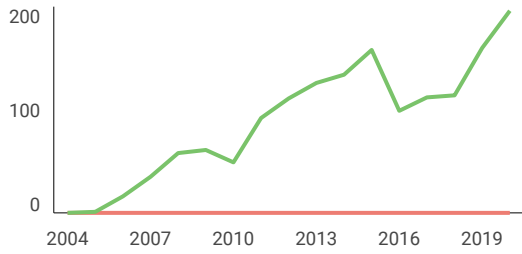
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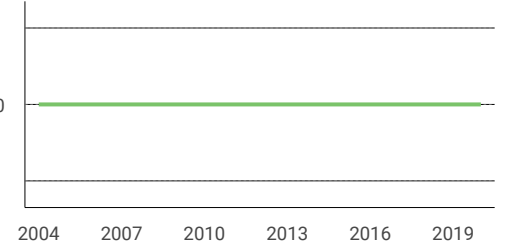
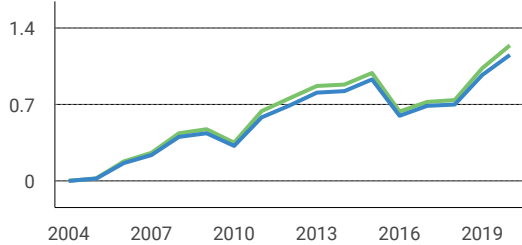
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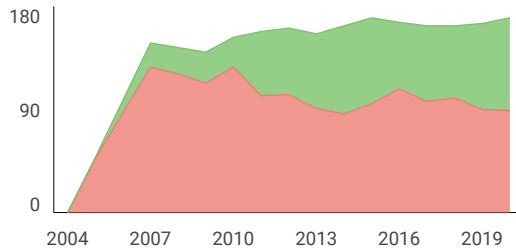
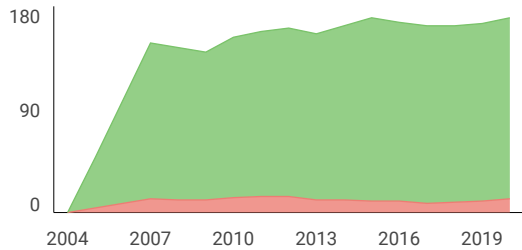
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Indonesia DIA-RAMADAN Study: A Real-life, Prospective and Observational of Gliclazide MR in Type-2 Diabetes Patients During Ramadan Fasting

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ABSTRACT

Background: Sulfonylureas (SUs) have been widely used in many countries for T2DM treatment. Gliclazide is one of the SUs with the lowest risk of hypoglycemia; however, the safety and effectiveness of gliclazide MR during Ramadan has not yet been reported in Indonesia. This study aimed to assess safety, efficacy, and tolerability of gliclazide modified release (MR) during Ramadan fasting. **Methods:** The study was a part of DIA-RAMADAN study, a prospective observational study with subjects of T2DM patients aged >18 years, who had either controlled or sub-optimally controlled blood glucose level, performed Ramadan fasting. Subjects had been treated with gliclazide MR for at least 90 days prior the study, and were examined for their body mass index (BMI), fasting plasma glucose (FPG) and HbA1c levels 6 to 8 weeks before Ramadan (V0) and 4 to 6 weeks after the end of Ramadan (V1). **Results:** Out of 198 subjects participating in the study, there were only two subjects (1.0%) who reported symptomatic HEs (either confirmed or not confirmed) and no severe HEs had been reported. There were no significant changes in HbA1c and FPG levels ($p > 0.05$). Interestingly, there was a reduction of bodyweight (-0.4kg) from pre- to post-Ramadan ($p < 0.001$). Almost no subjects reported discontinuation of gliclazide MR throughout the entire study; however, there was one subject who reported a change of diabetic treatment into diet only. **Conclusion:** gliclazide MR is safe, well tolerated and can maintain glycemic control effectively for Indonesian patients with T2DM who perform Ramadan fasting.

Keywords: type 2 DM, gliclazide MR, Ramadan, Indonesia.

INTRODUCTION

Indonesia, as a country with the largest Muslim population, has been projected with having 238 million of Muslim population in 2010.¹ With a prevalence of diabetes mellitus (DM) of 10.9% by year 2018, Indonesia has been ranked as a country with the seventh largest diabetes population in the world.^{2,3} Fasting during the holy month of Ramadan is an important event for Muslims and considered as one of the five pillars of Islam. Fasting for a long period could potentially affect the metabolic state of diabetes patients, including hypoglycemia, hyperglycemia, ketoacidosis, dehydration and increasing risk of complications.⁴ Patients in Indonesia fast for one month during Ramadan with at least 13 to 14 hours of fasting per day.⁵ There is no consensus about the most appropriate oral antidiabetic (OAD) agents for patients with T2DM to use during Ramadan.⁶

Sulfonylureas (SUs) remain the most commonly used OAD after metformin in Indonesia.⁷ It is well known that SUs were associated with a higher risk of hypoglycemia, which has raised some concerns about their use during Ramadan. Several studies demonstrate that many patients with T2DM may continue to use second-generation SUs and fast safely during Ramadan.^{6,8} Several randomised clinical trial (RCT) studies showed that gliclazide has lower risk of hypoglycaemia, even during fasting Ramadan, compared with other SUs. A newer formulation, modified release (MR) of gliclazide showed a lower risk of hypoglycemia, even during a fasting period when compared with other SUs.^{6,9,11}

The effectiveness and safety of gliclazide MR has not been studied during Ramadan in a real-life setting. The Indonesia-DIA-RAMADAN study, is a part of Global-DIA-RAMADAN study, which is conducted across countries in the Middle East, Africa, South, and South-east Asia. To our knowledge, our study represents the first real-life study of gliclazide MR in patients with T2DM who perform fasting during Ramadan. The aim of our study was to assess safety (based on HEs), efficacy (based on HbA1c changes), and tolerability of gliclazide MR in Indonesian Muslims with controlled or

suboptimal controlled T2DM (HbA1c < 9%) during Ramadan fasting.

METHODS

DIA-RAMADAN was a prospective and observational study conducted at 64 sites in 9 countries across the Middle East, Africa and Asia (Bangladesh, Egypt, India, Indonesia, Kuwait, Malaysia, Pakistan, Saudi Arabia and United Arab Emirates). Seven cities in Indonesia involved in this study were Jakarta, Surabaya, Yogyakarta, Makassar, Aceh, Solo, and Malang. The inclusion criteria were: subjects > 18 years of age with T2DM, body mass index (BMI) of ≥ 23 and < 30 kg/m², controlled or sub-optimally controlled T2DM (HbA1C < 9%); treated with gliclazide MR for at least 90 days prior to the initiation of the study (inclusion visit), either as monotherapy or in combination with any other diabetes treatment except insulin; experienced with self-monitoring of blood glucose (using blood glucose meter); subjects were willing to perform full (30 days) fast during Ramadan in 2019.

The study was conducted from mid-March 2019 to end of August 2019. The overall treatment duration consisted of pre-Ramadan period (6 to 8 weeks prior to the Ramadan), the Ramadan period (4.5 weeks), and post-Ramadan period (4 to 6 weeks after Ramadan) (**Figure 1**). During the first inclusion visit (V0), patient's demographic data, HbA1c and fasting plasma glucose (FPG) levels and body weight data were collected. Each patient was provided with a diary at V0 for recording the following events: (1) Any changes in their recommended oral antidiabetic therapy; (2) Any hypoglycemia-related symptoms experienced during the study; (3) Any other adverse events (AEs) occurred during the study.

Ethics

This study was approved by Ethical Committee of Health Research Ethics Committee (HREC) Faculty of Medicine, Brawijaya University (Reference no. 013/EC/KEPK/01/2019).

Study Assessment

Gliclazide MR was taken orally once daily at breakfast according to the summary of product

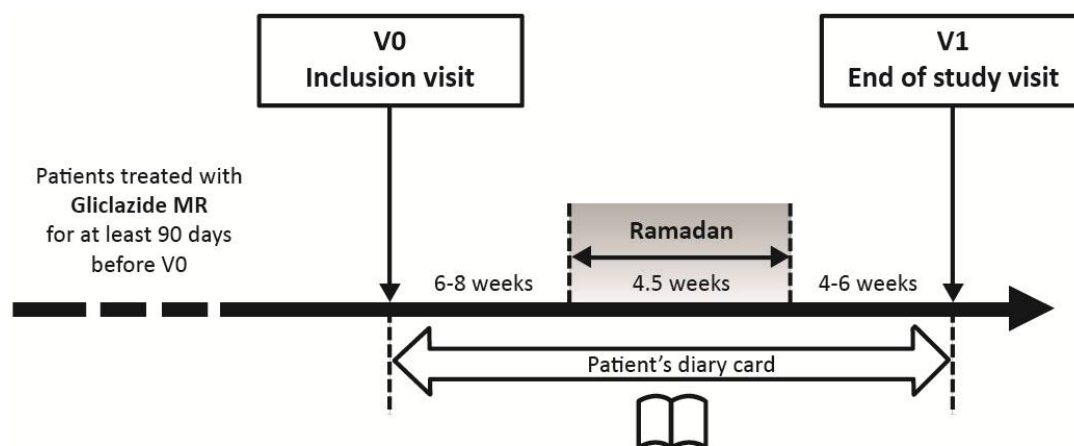


Figure 1. DIA- RAMADAN study protocol

characteristics (SmPC) until the beginning of Ramadan. During Ramadan¹¹, subjects were advised by their physician to take their gliclazide MR at iftar time (i.e., the post-sunset meal). Dose adjustment was based on direction of the investigator according to routine practice and local guidelines, if applicable. During the study, subjects continued receiving concomitant treatments for comorbid conditions.

Outcome Variables

The primary endpoint of the study was the proportion of subjects with at least one symptomatic hypoglycemia event (HE), either suggestive or confirmed by a measured glucose concentration of ≤ 70 mg/dL. Symptomatic hypoglycemia was defined as the presence of at least one of the following symptoms: sweating, pallor, tremor, intense hunger, pounding heart, visual disturbance, drowsiness, weakness, dizziness, cognitive impairment, unexplained behavior or mood change, confusion, headache; without or with a measurement of blood glucose. Severe hypoglycemia was defined as reported severe cognitive impairment requiring third-party assistance for recovery.^{12,13}

Secondary endpoints included changes of the following: HbA1c and FPG levels as well as body weight between V0 and V1; the proportion of subjects with at least one confirmed HE (asymptomatic or symptomatic); the proportion of subjects with at least one HE of any type. Any HE was defined as symptomatic hypoglycemia (confirmed or not) or confirmed asymptomatic hypoglycemia (asymptomatic with a measured

glucose concentration of ≤ 70 mg/dL).

Statistical Analysis

Two-sided statistical tests (paired t-test or Wilcoxon Signed Rank test) were applied with type I error (alpha), which was set at 5%. The Wilcoxon Signed Rank test was applied in cases of strong violation of normality. Statistical analyses were performed by Aixial (Boulogne-Billancourt, France). Analyses were conducted using SAS software, version 9.4 or higher (SAS Institute, North Carolina, USA). The values presented as means \pm standard deviation unless specified otherwise.

RESULTS

Patient Recruitment

Out of a total of 212 recruited patients, 198 patients were included in the final analysis set. Fourteen patients were excluded from the final analysis for reasons including noncompliance with inclusion/exclusion criteria and withdrawal of consent. Of the 198 patients examined at the inclusion visit (V0), 183 (92.4%) completed the study by attending the end of study visit (V1). The majority of patients who withdrew from the study did so due to non-medical reasons. Among 198 patients, 91 were male (46%) and 107 were female (54%), with average fasting day was 28.7 days. Contributing cities were Jakarta [24%], Surabaya [21%], Yogyakarta [17%], Makassar [16%], Aceh [10%], Solo [7%], and Malang [5%]. All subjects were included in the final analysis set.

Table 1. Baseline characteristics

Variable	Mean (SD)
Gender (%)	
Male	91 (46)
Female	107 (54)
Age (years)	57.4 (8.2)
Diabetes durations	3.9 (3.9)
Diabetes treatment	
Gliclazide MR (monotherapy)	84 (42.4)
Gliclazide MR + 1 Other OAD	84 (42.4)
Gliclazide MR + 2 others OAD	30 (15.2)
Comorbid conditions (%)	
Arterial hypertension	76 (38.4)
Dyslipidemia	84 (42.4)
Established cardiovascular disease	10 (5.1)
Diabetic neuropathy	9 (4.5)
Diabetic nephropathy	2 (1.0)
Diabetic retinopathy	1 (0.5)
Diabetic foot	1 (0.5)
Duration of Fasting (days)	28.7 (3.5)
Laboratory values	
HbA1c, (%)	7.4 (0.9)
FPG, (mg/dL)	134.5 (42.4)
Serum Creatinine, (mg/dL)	0.91 (1.02)

FPG, fasting plasma glucose; OAD, oral anti diabetic; HbA1c, glycated hemoglobin; SD, standard deviation

Baseline Patterns of Antidiabetic Medication Use

Of 198 patients, 84 patients were using gliclazide MR as monotherapy (42.4%) and 114 patients were using gliclazide MR in combination with other antidiabetic agents (**Figure 2**). The mean daily dose of gliclazide MR was 65 mg. No dose modification in gliclazide MR treatment was observed during the study.

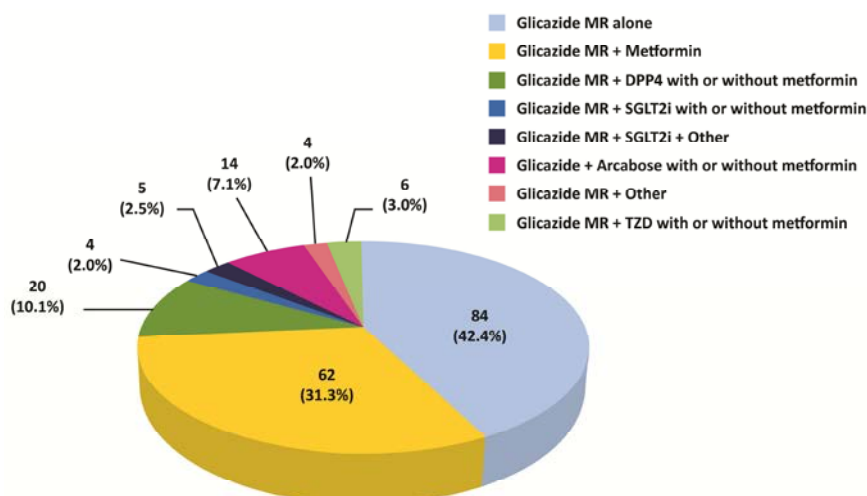


Figure 2. Antidiabetic treatment at baseline (v0). DPP4, dipeptidyl peptidase 4 inhibitor; GLP1 RA, glucagon-like peptide-1 receptor agonist; MR, modified release; SGLT2i, sodium-glucose cotransporter 2 inhibitor; TZD, thiazolidinedione.

Safety and Tolerability

Hypoglycemia event under gliclazide MR treatment during Ramadan fasting in Indonesia was very low; there were only two subjects (1%) experiencing at least one hypoglycemia episode during the period of fasting, i.e., one subject (0.5%) with symptomatic hypoglycemia and one patient (0.5%) with confirmed hypoglycemia. No subjects reported severe hypoglycemia.

Adverse Effects (Other Than HEs)

The most commonly reported AEs in the study were vertigo and gastrointestinal disorders. In clinical experiences, gliclazide MR does not cause vertigo and gastro-intestinal symptoms but we cannot confirm whether these vertigo and gastro-intestinal complaints are related to medication or fasting. No subjects experienced any drug-related AEs during the study.

Tolerability

During the study period, there was only one subject who discontinued the gliclazide MR treatment and changed it with lifestyle modification according doctor's advice. Our results showed that gliclazide was well tolerated by almost all subjects.

Efficacy

HbA1c and FPG levels were examined at visits V0 and V1 (**Figure 3A**). There was no significant change of HbA1c and FPG ($p > 0.05$) levels between both study visits. There were increased number of subjects with HbA1c level of

<7.5% from 99 to 109 subjects and from 0 to 13 subjects with HbA1c >9%, indicating that there was improved glycemic control in 10 subjects and worsened in 13 subjects. (Figure 3B).

(HbA1c [n = 182] and FPG [n = 182] at V1). FPG, fasting plasma glucose; HbA1c, glycated

hemoglobin; SD, standard deviation.

Body Weight

Significant reductions in body weight (0.4 kg) were recorded between visits V0 and V1 (p < 0.001) (Figure 4).

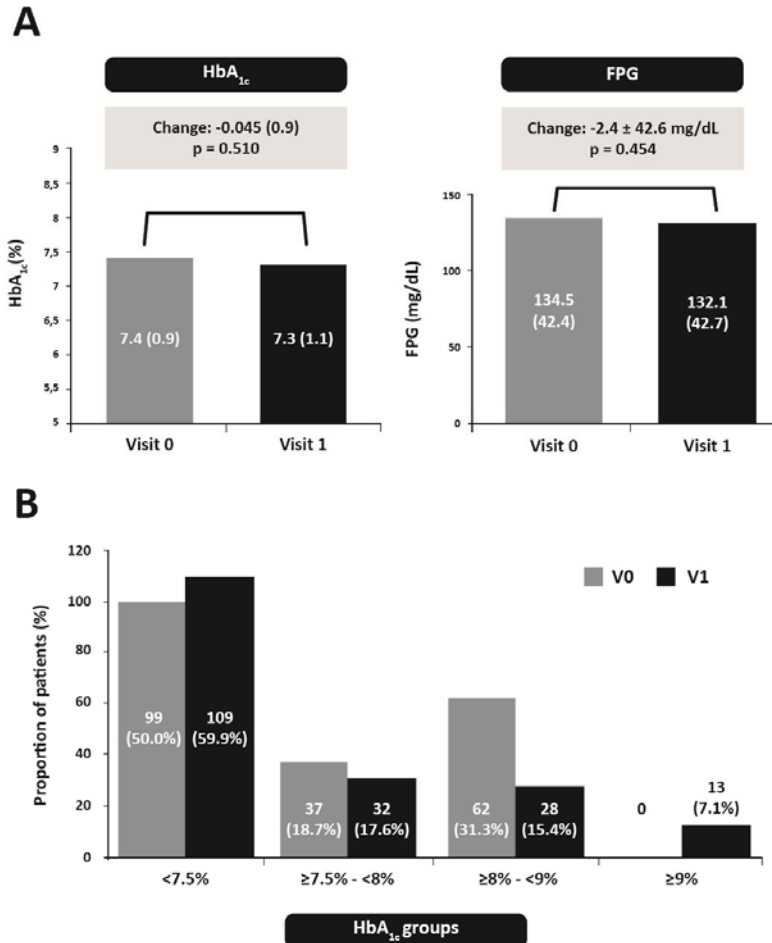


Figure 3. HbA1c and FPG levels at V0 and V1. (A) Mean HbA1c and FPG levels at V0 and V1. (B) Proportion of patients within specified HbA1c range at V0 and V1.

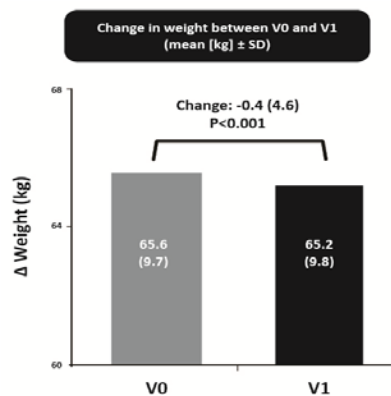


Figure 4. Mean body weight at V0 and V1. (n = 184). SD, standard deviation.

DISCUSSION

Sulfonylureas have been extensively used as treatment of type-2 diabetes for nearly 70 years.¹⁴ The most common choice for second-line therapy in patients who require additional glucose-lowering during metformin monotherapy were SUs and DPP-4is.¹⁵

To our knowledge, DIA-RAMADAN is the first real-life observational study assessing the efficacy and safety of gliclazide MR 60 mg in patients with controlled or sub-optimally controlled T2DM during Ramadan fasting. In line with the results from previous observational studies, gliclazide (IR or MR) showed a lower incidence of HEs compared with other SUs in this study. A large observational study evaluating the incidence of HEs in patients with T2DM treated with glipizide, glimepiride, gliclazide (IR or MR), or glibenclamide showed that 14% of those treated with gliclazide experienced at least one symptomatic HE during Ramadan, which was notably lower than values reported for other SUs (glipizide [27.6%], glibenclamide [25.6%] and glimepiride [16.8%]).¹⁶

The reduced rate of HEs with gliclazide compared with other SUs could be explained by differences in its pharmacokinetic and pharmacodynamics properties, mechanism of action and insulin excretion profile. Sulfonylureas stimulate secretion of insulin from pancreatic β -cells via a blockade of ATP-sensitive K-channels (KATP), resulting in membrane depolarisation, calcium influx and insulin release. While glibenclamide provides irreversible inhibition of the Kir6.2/SUR1 KATP channel, inhibition by gliclazide is rapidly reversible.

A previous study examining hypoglycemia in patients with T2DM receiving sitagliptin or an SU during Ramadan showed that incidence of hypoglycaemia was similar between sitagliptin and gliclazide. The proportion who reported symptomatic HEs in sitagliptin group was 6.7% compared with 6.6% of patients treated with gliclazide MR.⁶ Additionally, the proportion of patients treated with gliclazide MR with at least one symptomatic HE during Ramadan was reported to be as low as 1.8% in one study (compared with glibenclamide [5.2%] and glimepiride [9.1%]).¹⁰

The ultimate goal of diabetes treatment during Ramadan is to sustain glycemic control during fasting period with low risk of hypoglycemia in patients with T2DM¹⁷. Our results presented here show that gliclazide-treated patients experienced a stable level of HbA1c and FPG as well as a significant reduction of body weight between study visits. As no dose changes were reported during the study, patients treated with gliclazide MR can therefore continue with pre-Ramadan dosing levels during fasting. There was a higher proportion of patients having an HbA1c value $\geq 9\%$ at V1 versus V0 (6.6%) compared to DIA-RAMADAN global study.¹⁸ This different result could be related to change of meal composition during Ramadan since there was no report of any change in diabetic treatment except one subject reporting discontinuation of gliclazide MR and dietary change only during the study period.

Our study has several limitations, including the biases that are typically associated with non-comparative observational study designs. In addition, the study enrolled patients were already receiving gliclazide MR at stable doses for 90 days prior to the inclusion visit. This suggests that the study drug was well tolerated in these patients. Other relevant biases include underreporting of adverse events and hypoglycemic episodes, particularly those that were self-reported in patients' diaries, as well as recall bias. At visit V0, patients were advised about changes required to the timing of their gliclazide MR dose during the month of Ramadan according to current IDF-DAR guidelines at the discretion of the treating physician.

Results of our study show real-life evidences gathered by the investigators according to their standard clinical practice. Treatment adherence to gliclazide MR during Ramadan in Indonesia is high (98.8%). Majority of patients (92.4%) who attended the inclusion visit (V0) also attended the end-of study visit (V1), and only a few data were missing considering the observational nature of the study.

CONCLUSION

In Indonesian population, gliclazide MR either as monotherapy or combinations with other OADs has been shown to be an effective, safe and

well-tolerated treatment in patients with T2DM who perform fasting during Ramadan with a consistently low incidence of hypoglycemia, whilst maintaining glycemic control.

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