

## BIOCHEMICAL INSIGHTS AND HORMONAL MARKERS OF POLYCYSTIC OVARY SYNDROME IN SUDANESE WOMEN: EXPLORING INFERTILITY AND RISK FACTORS IN RED SEA STATE

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### Abstract.

**Introduction:** Polycystic Ovary Syndrome (PCOS) is a prevalent hormonal condition affecting women of reproductive age, with prevalence rates ranging from 5% to 13%. Symptoms include irregular menstrual cycles, androgen excess, hair growth, acne, and cysts in the ovaries, often seen during adolescence. **Aim:** The purpose of this study was to investigate the hormonal and biochemical profiles of women with PCOS in the Red Sea State, Sudan with a focus on infertility and associated risk factors. **Materials and methods:** This cross-sectional study involved 40 women with a Rotterdam-defined PCOS diagnosis and 40 healthy control subjects. Participants provided demographic information, including age, family history, irregular menstruation, infertility, metabolic abnormalities, and clinical symptoms. Serum was extracted to estimate hormonal profiles, and enzymatic techniques were used to analyze fasting blood glucose and lipid profiles, while ELISA quantitative methods were used for hormone profiles. **Results:** The study found that 40% of patients were aged 20-30, 45% were with primary schools' education level, 53% had low economic status, 58% had abnormal menstrual cycle features, 60% had a positive case history, 75% did not have chronic disease characteristics, 68% had infants, and 83% had normal body mass index. The study found an insignificant correlation between infertility hormones and lipid profiles in patients, with FSH, LH, and LDL showing insignificant variation, while PRL, Chol, TG, and HDL showed significant correlations. **Conclusion:** The study reveals significant changes in lipid and hormonal profiles in Sudanese women with PCOS, even those with normal BMI. Although cyst laterality doesn't strongly correlate with clinical indicators, more research is needed to understand its relationship with LH and chronic illness. Early screening and multidisciplinary therapy are crucial due to high incidence of dyslipidemia, positive family history, and irregular menstruation.

**Key words.** ELISA, Polycystic Ovary Syndrome (PCOS).

### Introduction.

Polycystic ovarian syndrome (PCOS), first described in 1935, is the most common endocrine pathology in female reproductive health, with prevalence ranging from 5% to 15%, diagnosed by chronic anovulation, hyperandrogenism, and polycystic ovaries [1].

According to a meta-analysis and systematic review, the overall prevalence of infertility in Sudan is roughly 13%, with 35% of cases being secondary infertility and 65% being primary infertility. Ovulatory abnormalities are common in infertile women, and PCOS accounts for 38% of these cases. Various factors lead to an increased prevalence of the disease, unknown prevalence on Sudan besides different diagnostic criteria used for diagnosis as well as the absence of screening program and genetic counseling in addition to the lack of awareness through the community about the importance of women health and its impact on her social life [2].

The typical biochemical abnormalities include increased levels of serum androgens (especially testosterone and androstenedione) and elevated Luteinizing Hormone (LH) levels, while Follicle-Stimulating Hormone (FSH) levels remain normal or are low [3].

Based on the "Rotterdam criteria," PCOS is diagnosed when two of the three characteristics—polycystic ovaries, anovulation, and androgen excess (clinical and/or biochemical)—are present [4]. The 2023 International PCOS Guideline criteria revise Rotterdam criteria, recommending diagnosis in adults based on oligo/amenorrhea, clinical/biochemical hyperandrogenism, and PCOM, and adolescents requiring both [5,6].

Many of the endocrine characteristics of PCOS seem to be caused by insulin resistance and its subsequent hyperinsulinemia in a significant number of these patients. Patients with PCOS have a five to ten times higher chance of developing type 2 diabetes mellitus than the general population [7].

PCOS is also a major contributor to infertility in women. For women with PCOS, improvements in lifestyle, such as decreasing weight, can lead to physical changes that make conception easier [8].

PCOS, including obesity, hirsutism, hair loss, irregular menstruation, and acne, can lead to low self-esteem, social rejection, and psychological problems. It also increases anxiety, depression, and loneliness, contributing to higher divorce rates and strained marriages.

Cultural, environmental, and genetic factors in Sudan may influence PCOS presentation and progression. Limited research on biochemical and hormonal underpinnings is crucial for effective diagnosis, management, and risk mitigation.

The purpose of this study is to investigate the hormonal and biochemical profiles of women with PCOS in the Red Sea State, with a focus on infertility and associated risk factors. By detecting patterns and connections, the study hopes to reveal insights that can improve diagnostic precision and inform targeted therapies. Furthermore, it investigates the impact of local environmental and lifestyle factors in regulating the clinical symptoms of PCOS, contributing to a better understanding of the disease in a geographically and culturally diverse population.

### Materials and Methods.

This an analytical laboratory-based cross-sectional study to investigate the hormonal and biochemical profiles of women with PCOS in the Red Sea State, with a focus on infertility and associated risk factors.

This cross-sectional study involved 40 women with a Rotterdam-defined PCOS diagnosis and 40 healthy control subjects. Participants provided demographic information, including age, family history, irregular menstruation, infertility, metabolic abnormalities, and clinical symptoms.

Any Sudanese females below the reproductive age, females with family history of adrenal hyperplasia, hyperprolactinemia, Cushing syndrome, thyroid disorders, ovarian cancer or breast cancer and causes of infertility rather than PCOS were excluded from the study.

Structured self-administered questionnaires were answered by study participants covering their; socio-demographic variables: Age, family history, menstrual abnormalities, infertility problems, metabolic abnormalities and clinical symptoms.

Venous blood was drawn from patients and controls with a disposable sterile plastic syringe. After a 10-minute centrifugation at 5000 RPM at room temperature, serum is recovered and stored at -80 °C.

Data was input and structured into a Microsoft Office Excel (2019) data sheet before being transferred to the statistical package program IBM SPSS Statistics for Windows, Version 26.049 to perform various statistical tests such as mean standard deviation and P-value.

For hormonal profile estimations, we used quantitative (ELISA) and enzymatic methods to analyze fasting blood glucose and lipid profile.

Shendi University's ethical committee approved the study, and participants provided their consent.

### Results.

This analytical, laboratory-based cross-sectional study was conducted to investigate various biochemical parameters in 40 Sudanese individuals with one or more female family members diagnosed with PCOS, alongside 40 individuals in a control

group. Descriptive and biological data were collected using a self-administered questionnaire. The information was analysed using SPSS version 26, with descriptive statistics applied to assess the frequency distributions of age (years), BMI, clinical signs and symptoms, and biochemical markers.

For both categories, the largest percentage of participants are in the 20–30 age range (Figure 1).

Compared to the control group, PCOS patients are more likely to have completed primary school. Both groups have comparable levels of secondary education. Although there are fewer women in both groups with a university degree, the case group's percentage is marginally greater (Figure 2).

The majority of women in both groups are low-income, the prevalence of PCOS is almost the same in the moderate-income group as it is in the controls, and there are more PCOS patients in the high-income group than in the controls (Figure 3).

Compared to healthy controls, women with PCOS have a higher prevalence of chronic illnesses, especially diabetes and hypertension (Figure 4)

75% of PCOS patients had abnormal menstruation compared to 67.5% in the control group Confirms that menstrual irregularity is more common in PCOS (Table 2), 60% of the PCOS group had a positive family history, suggesting a hereditary component in PCOS development (Table 3).

Only 50% of PCOS patients had regular medical follow-up indicates gaps in healthcare access or awareness (Table 3), 53% had bilateral cysts, 47% had unilateral suggest that bilateral involvement is slightly more common (Table 4) 68% of PCOS patients had a history of childbirth Implies that fertility is possible, though PCOS is a known infertility risk (Table 5).

83% had normal BMI, 17% were overweight Most PCOS patients in this sample were non-obese, highlighting that PCOS isn't limited to obese women (Table 6)

No significant associations found between cyst location and menstruation ( $p=0.2$ ), family history ( $p=0.5$ ), medical follow-up ( $p=0.1$ ) and history of delivery ( $p=0.5$ ) while Significant association found with: Chronic disease ( $p=0.04$ ), especially diabetes, which was more common in those with bilateral cysts (Tables 7-11)

Significant differences in PRL, Cholesterol, Triglycerides, and HDL (all  $p < 0.01$ ) – all higher in PCOS group while no significant differences in FSH, LH, and LDL (Table 12).

Significant difference in LH levels ( $p = 0.01$ ) higher in those with unilateral cysts however no significant differences in other hormones or lipids by cyst location (Table 13).

No statistically significant differences between regular and irregular menstruation in hormonal or lipid values with some trends (e.g., higher PRL in regular cycles), but not significant (Table 14).

No significant differences between normal and overweight groups, Overweight group had higher TG and lower HDL, but not statistically significant (Table 15).

### Discussion.

This analytical, laboratory-based cross-sectional study aimed to assess biochemical and clinical parameters associated with polycystic ovary syndrome (PCOS) among Sudanese women with familial PCOS history, compared to a control group. The

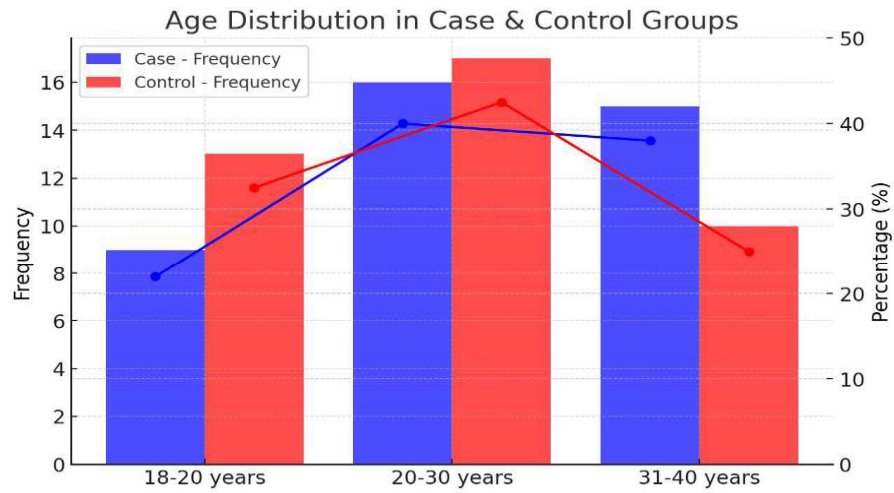


Figure 1. Age Distribution in Case and Control Groups.

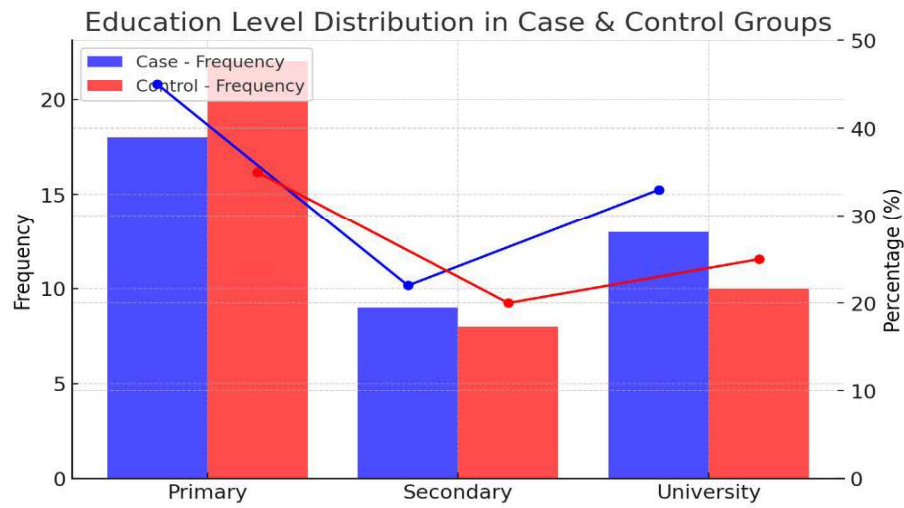


Figure 2. Education Level Distribution in Case and Control Groups.

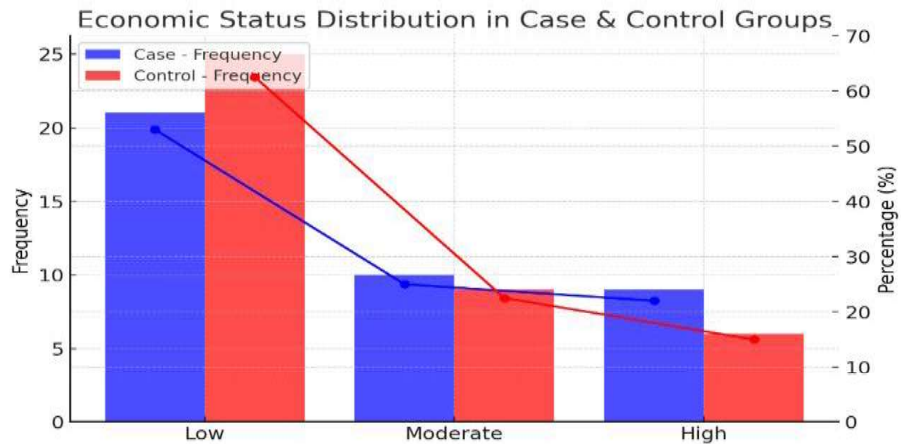


Figure 3. Economic Status Distribution in Case and Control Groups.

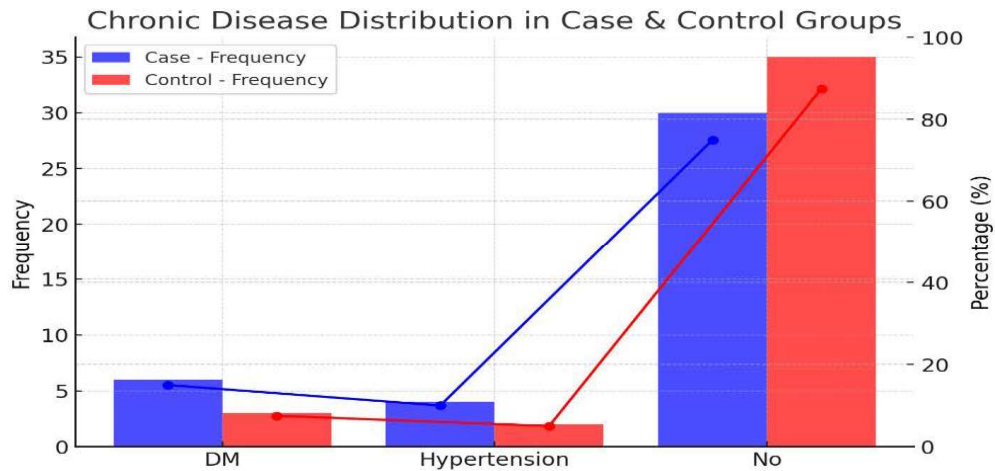


Figure 4. Chronic Disease Distribution in Case and Control Groups.

Table 1. Menstruation status patients and control under study.

Menstruation status		Frequency	Percent
Normal	Case	10	25%
	Control	13	32.5%
Abnormal	Case	30	75%
	Control	27	67.5%
Total		80	100%

Table 2. Family history in case group.

Family history	Frequency	Percent
Positive FH	24	60%
Negative FH	16	40%
Total	40	100%

Table 3. Medical follow up in case group.

Follow up	Frequency	Percent
Positive follow up	20	50%
Negative follow up	20	50%
Total	40	100%

Table 4. Cyst location in case group.

Cyst location	Frequency	Percent
Unilateral	19	47%
Bilateral	21	53%
Total	40	100%

Table 5. History of delivery in case group.

Patient has delivered before	Frequency	Percent
Yes	27	68%
No	13	32%
Total	40	100%

Table 6. BMI in case group.

BMI	Frequency	Percent
Normal	33	83%
Overweight	7	17%
Total	40	100%

Table 7. Association between cyst location and menstruation cycle status.

Cycle status		Cyst		Total	P.value
		Uni	Bi		
Normal	Count	7	15%	4	0.2
	%	17.5%	37.5%	10.0%	
Abnormal	Count	12%	6	4	
	%	30%	15%	10.0%	
Total	Count	19	21	40	
	%	100.0%	100.0%	100.0%	

The mean difference is significant at the (0.05) level.

Table 8. Association between cyst location and family history in patients.

Case history		Cyst		Total	P.value
		Uni	Bi		
Positive	Count	11	13	24	0.5
	%	27.5%	32.5%	60.0%	
Negative	Count	8	8	16	
	%	20	20%	40.0%	
Total	Count	19	21	40	
	%	100.0%	100.0%	100.0%	

\*The mean difference is significant at the (0.05) level.

Table 9. Relation between cyst location &amp; medical follow up in patients.

Management		Cyst		Total	P.value
		Uni	Bi		
Positive	Count	7	13	20	0.1
	%	17.5%	32.5%	50.0%	
Negative	Count	12	8	20	
	%	30%	20%	50.0%	
Total	Count	19	21	40	
	%	100.0%	100.0%	100.0%	

\*The mean difference is significant at the (0.05) level.

Table 10. Association between cyst location and chronic diseases in patients.

Disease		Cyst		Total	P.value
		Uni	Bi		
DM	Count	0	6	6	0.04
	%	0.0%	15%	15.0%	
Hypertension	Count	2	2	4	
	%	5%	2%	10.0%	
No Disease	Count	17	13	30	
	%	42.5%	32.5%	75.0%	
Total	Count	19	21	40	
	%	100.0%	100.0%	100.0%	

\*The mean difference is significant at the (0.05) level.

Table 11. Association between cyst location &amp; and delivery in patients.

Infant		Cyst		Total	P.value
		Uni	Bi		
Yes	Count	13	14	27	0.5
	%	32.5%	35%	67.5%	
No	Count	6	7	13	
	%	15%	17.5%	32.5%	
Total	Count	19	21	40	
	%	100.0%	100.0%	100.0%	

\*The mean difference is significant at the (0.05) level.

Table 12. Correlation between infertility hormones and lipid profile (case & control) in patients.

Sample		N	Mean	Std. Deviation	P.value
FSH (ng/dl)	Case	40	5.6	3.0	0.3
	Control	40	5.0	2.3	
LH (ng/dl)	Case	40	8.1	2.8	0.3
	Control	40	7.5	2.5	
PRL (ng/dl)	Case	40	31.2	12.8	0.00
	Control	40	14.7	5.5	
Chol (mmol/l)	Case	40	9.0	1.3	0.00
	Control	40	5.0	0.3	
TG (mmol/l)	Case	40	7.6	2.2	0.00
	Control	40	3.3	1.8	
HDL (mmol/l)	Case	40	4.0	1.7	0.00
	Control	40	1.8	0.3	
LDL (mmol/l)	Case	40	5.0	2.0	0.7
	Control	40	4.7	1.8	

\*The mean difference is significant at the (0.05) level.

Table 13. Correlation between infertility hormones & lipid profile with cyst location in patients.

Cyst		N	Mean	Std. Deviation	P.value
FSH (ng/dl)	Uni	19	3.9	1.6	0.08
	Bi	21	6.0	3.6	
LH (ng/dl)	Uni	19	9.0	2.1	0.01
	Bi	21	6.2	2.7	
PRL (ng/dl)	Uni	19	30.7	13.3	0.9
	Bi	21	31.5	12.7	
CHOL (mmol/l)	Uni	19	5.2	1.4	0.5
	Bi	21	5.5	1.3	
TG (mmol/l)	Uni	19	2.5	1.8	0.1
	Bi	21	4.1	2.3	
HDL (mmol/l)	Uni	19	3.8	1.6	0.7
	Bi	21	4.2	1.7	
LDL (mmol/l)	Uni	19	4.6	2.1	0.4
	Bi	21	5.0	2.0	

\*The mean difference is significant at the (0.05) level.

Table 14. Correlation between infertility hormones & lipid profile with menstruation in patients.

cycle status		N	Mean	Std. Deviation	P.value
FSH (ng/dl)	Irregular	23	4.7	2.6	0.6
	Regular	9	4.1	1.3	
LH (ng/dl)	Irregular	23	7.0	3.0	0.1
	Regular	9	9.1	1.3	
PRL (ng/dl)	Irregular	23	27.1	13.0	0.09
	Regular	9	39.4	8.1	
CHOL (mmol/l)	irregular	23	5.2	1.3	0.6
	Regular	9	5.6	1.4	
TG (mmol/l)	irregular	23	3.9	2.6	0.3
	Regular	9	2.9	1.2	
HDL (mmol/l)	irregular	23	3.6	1.7	0.4
	Regular	9	4.3	0.5	
LDL (mmol/l)	irregular	23	4.7	2.4	0.4
	Regular	9	4.2	1.3	

\*The mean difference is significant at the (0.05) level.

Table 15. Association between infertility hormones&amp; lipid profile with BMI in patients.

BMI		N	Mean	Std. Deviation	P.value
FSH (ng/dl)	Normal	33	5.3	3.2	0.4
	overweight	7	3.9	1.7	
LH (ng/dl)	Normal	33	7.8	2.7	0.4
	overweight	7	6.3	3.0	
PRL (ng/dl)	Normal	33	31.4	13.9	0.8
	overweight	7	30.0	5.9	
CHO (mmol/l)	Normal	33	5.6	1.3	0.2
	overweight	7	4.6	1.3	
TG (mmol/l)	Normal	33	2.9	1.9	0.1
	overweight	7	5.3	2.4	
HDL (mmol/l)	Normal	33	3.8	1.8	0.3
	overweight	7	4.9	0.4	
LDL (mmol/l)	Normal	33	5.0	2.1	0.2
	overweight	7	4.1	1.6	

\*The mean difference is significant at the (0.05) level.

study provides several notable insights into the clinical features, hormonal profiles, lipid levels, and cystic characteristics associated with PCOS in this population.

Menstrual abnormalities were significantly more prevalent in the case group (75%) compared to controls (67.5%), consistent with the established role of PCOS in causing menstrual dysfunction. A substantial portion of the case group (60%) also reported a positive family history, reinforcing the genetic and familial contribution to PCOS pathogenesis. Despite this, no statistically significant association was found between family history and cyst location ( $p = 0.5$ ), suggesting that cyst laterality may not be directly influenced by familial factors in this cohort.

In the case group, bilateral ovarian cysts were slightly more common (53%) than unilateral cysts (47%). However, there was no statistically significant association between cyst location and most clinical variables, including menstruation status ( $p = 0.2$ ), medical follow-up ( $p = 0.1$ ), and history of delivery ( $p = 0.5$ ). A significant finding was observed between cyst location and chronic disease status ( $p = 0.04$ ), with bilateral cysts being more associated with diabetes mellitus, indicating a potential link between more extensive ovarian involvement and metabolic disturbances.

The majority of participants in the case group had normal BMI (83%), with 17% classified as overweight. Despite this, lipid abnormalities were prominent. The case group demonstrated significantly elevated levels of total cholesterol, triglycerides (TG), HDL, and PRL compared to controls (all  $p < 0.01$ ), while LDL levels did not differ significantly. This suggests a PCOS-related dyslipidemia that may occur independently of BMI, aligning with evidence that PCOS is a metabolic disorder even in non-obese women.

When assessing the relationship between BMI and biochemical markers, no significant differences were observed, although overweight individuals tended to have higher TG levels (mean = 5.3 mmol/L) compared to those with normal BMI (mean = 2.9 mmol/L), suggesting a trend worth further exploration.

Among infertility-related hormones, prolactin (PRL) levels were significantly higher in the case group (mean = 31.2 ng/dL) compared to controls (mean = 14.7 ng/dL,  $p = 0.00$ ), reflecting

hyperprolactinemia's possible role in PCOS pathophysiology. However, FSH and LH levels, while slightly elevated in the case group, did not differ significantly.

Notably, LH levels were significantly associated with cyst location ( $p = 0.01$ ), with unilateral cysts showing higher LH levels, suggesting a potential link between hormonal regulation and the extent of ovarian involvement. However, other hormonal markers (FSH, PRL) and lipid profiles did not significantly vary with cyst laterality.

More than two-thirds of the case group had a history of delivery (68%), and half reported regular medical follow-up. These findings reflect varied reproductive outcomes among women with PCOS and indicate that access to care may not be uniform across the population.

## Conclusion.

This study highlights significant hormonal and lipid profile alterations in Sudanese women with PCOS, even in those with normal BMI. While cyst laterality does not appear to correlate strongly with most clinical parameters, its association with LH and chronic disease warrants further investigation. The high prevalence of menstrual irregularities, positive family history, and dyslipidemia emphasizes the need for early screening and multidisciplinary management of PCOS, particularly in regions where awareness and access to care may be limited.

## Acknowledgment.

We would like to express our gratitude to all participants involved in the study.

## Funding.

This study has not received any external funding.

## Conflict of interest.

The authors declare that there is no conflict of interest.

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