

Shifting the Paradigm in GDM Care: A Randomized Controlled Trial of Midwifery-Led Versus Standard Care on Birth and Emergency Complication Preparedness Performance

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Abstract

Background: Gestational Diabetes Mellitus (GDM) is a high-risk illness linked to poor maternal and newborn outcomes. Adequate birth preparedness and complication readiness (BPCR) are critical components of safe motherhood, especially for women with GDM. Midwifery-led forms of care have demonstrated the ability to improve maternal outcomes via ongoing support, education, and empowerment.

Objective: The objective is to assess the impact of a midwifery-led care paradigm on birth preparedness and complication readiness for pregnant women with GDM.

Methods: A randomized controlled trial was carried out on 180 pregnant women diagnosed with GDM at a tertiary care facility. Using simple random sampling, participants were randomly assigned to the experimental (n=90) and control (n=90) groups. The experimental group received a structured midwifery-led intervention that included personalized instruction, counseling, and follow-up support, while the control group received standard care. Data were gathered using a structured demographic questionnaire and a standardized Birth Preparedness and Complication Readiness (BPCR) assessment form. The sample size was obtained using power analysis (power 80%, $\alpha=0.05$, effect size 0.5) to account for potential attrition. The data were examined using descriptive and inferential statistics, such as the independent t-test and the chi-square test.

Results: After intervention, the experimental group significantly improved their BPCR scores compared to the control group ($p<0.05$). The findings show that the midwifery-led program improved expectant moms' readiness for labor and awareness of obstetric problems.

Conclusion: Midwifery-led care is helpful in improving birth preparedness and complication readiness for expectant women with GDM. Integrating such models into routine antenatal treatment can help to enhance maternal and newborn outcomes.

Keywords: Gestational Diabetes Mellitus, Midwifery-led care, Birth preparedness, Complication readiness, Randomized controlled trial

Introduction

GDM is a metabolic disorder in pregnant women with glucose intolerance, which was detected for the first time during the pregnancy and is associated with several complications including preeclampsia and caesarean delivery [1]. Also, several negative consequences for the neonate include macrosomia, delivery trauma, and metabolic problems [2]. Also, women with GDM have a high risk of getting type 2 diabetes or any other metabolic disorder in the future, and the same risk applies to their children [3]. There has been a rise in the incidence of GDM worldwide, especially in developing nations, over the past decade, owing to obesity, sedentary lifestyle, and late childbirth.

The burden has put a lot of pressure on the maternal health-care systems, especially in developing countries where there are no proper resources available for excellent care [8]. Pregnancy with poorly controlled glycemia may result in complications such as hypoglycemia of a newborn child, breathing issues, and unusual patterns of fetal development [9]. These outcomes emphasize the necessity for early identification, monitoring, and management of gestational diabetes during pregnancy. [5].

The antenatal care process plays an important role in the early identification and management of GDM and risks that may occur along with it [3]. Prenatal interventions like nutritional counseling, exercise, glycemic monitoring, and patients' education have proved effective for improvement of blood sugar level control and gestational outcomes. Patient-centered care promotes compliance with treatment and allows patients to take an active part in their treatment [5].

The midwife-led model of care became internationally recognized as highly effective for improving the health condition of pregnant women by providing continuity of care and personalized assistance [4]. These techniques center on holistic care, respectful maternity care, and close ties between patients and their providers. Research shows that midwife-centered care results in greater maternal satisfaction, less medical intervention, and improved childbirth experiences without compromising safety [6].

Birth preparedness and complication readiness (BPCR) is an important part of maternal health care and is meant to minimize any delay in seeking specialist help during childbirth [7]. BPCR includes securing an attending birth professional, finding a place of delivery, securing means of transport, and financial preparedness for any emergency. Even though it is very crucial, most women with gestational diabetes mellitus remain unprepared for childbirth because of a lack of information and inadequate counseling in antenatal visits [8]. Lack of access to health care facilities, financial constraints, and ignorance all affect antenatal care attendance [7].

Moreover, efficient GDM management requires a multidisciplinary approach, including timely identification and regular screening to prevent complications [9]. Recent research has confirmed that the application of innovative therapeutic models, for instance, midwife-led initiatives, is possible and may contribute to better involvement and outcomes of patients [10]. Respectful maternity care, encompassing dignity, communication, and psychological support, was associated with increased well-being of women and their engagement in healthcare services [11]. In addition, patient-centered therapy during labor improves the entire experience of childbirth and contributes to healthy behaviors [12]. Perception of the quality of care has a considerable influence on the willingness of women to visit and utilize maternal health services [13].

The delayed initiation and underutilization of prenatal therapies are often associated with lack of perceived need and incorrect understanding of risks related to pregnancy [14]. Transportation problems, geographical inaccessibility, and absence of healthcare infrastructure are some of the key obstacles to prenatal care [15]. Anxiety, fear, and negative encounters with healthcare professionals play a role in the reluctance to obtain prompt healthcare [16]. Financial obstacles including the inability to afford health care services continue to be a major obstacle, especially in underdeveloped settings [17]. Long waiting periods, overcrowding, and scarcity of healthcare professionals account for the lack of access to quality maternal care [18].

Inability to understand available healthcare services and benefits associated with timely prenatal care play a great role in delaying maternal care seeking and poor maternal outcomes [19]. While midwifery care programs have proved to be promising regarding maternal and neonatal outcomes, there is not enough research done in an effort to evaluate its usefulness in preparing birth and complication preparedness, especially with GDM [6].

The current research is mostly focused on clinical outcomes, while neglecting issues related to preparedness and behavioral aspects of care seeking [5].

As a result, well-designed randomized controlled trials are necessary for determining the efficacy of midwifery-led forms of care in enhancing birth preparedness and complication readiness among pregnant women with GDM. Such evidence is critical for strengthening maternal healthcare policies and improving outcomes in this high-risk population.

Materials and Methods

Study design and setting

The current study employed a quantitative research approach utilizing a parallel-group, two-arm randomized controlled trial (RCT) design. This study was intended to examine the efficacy of the midwifery-led model of care on the promotion of BPCR among antenatal patients suffering from gestational diabetes mellitus (GDM) at a tertiary care facility located in Bhubaneswar, Odisha. The target population of the study consisted of pregnant women who were suffering from GDM.

Study Participant and Eligibility Criteria

The recruitment of participants took place based on inclusion criteria which include diagnosis of GDM, age 28-34 weeks of gestation at the time of recruiting, age 18 years or above, consented to give written informed consent, and capable of reading and understanding the Odia or English language. Excluded from participating in the study were women who had other risk factors in their pregnancies such as preeclampsia, eclampsia, antepartum bleeding, placenta previa, or multiple pregnancies. Also excluded were women with underlying severe health conditions. Consecutively recruited GDM women were included in the study until adequate sample size was obtained.

Sample Size Calculation and Correction

The a priori power analysis was carried out in order to estimate the necessary number of subjects to detect any significant difference between the BPCR scores in both groups. Taking into consideration the two-sided significance level $\alpha = 0.05$, 80% power, and moderate effect size (Cohen's $d = 0.5$), the number of subjects needed to be 81 per each group. In order to make sure that there will be at least 90 participants per each group taking into consideration the expected 10% attrition rate, 200 women were recruited in total.

Randomization and Allocation Concealment

After the recruitment and pre-test assessment of the participants, those eligible for participation were randomized to either the experimental (midwifery care group) or the control (standard care group). This randomization was done using a computerized random number algorithm where each individual had an equal probability of assignment to either group. In order to have strict

allocation concealment, the sequence of random allocation was put in sealed opaque envelopes. The envelopes would be opened in order after each participant had been recruited and had undergone pre-test assessments. This prevented the researchers as well as the participants from predicting group allocation before recruitment.

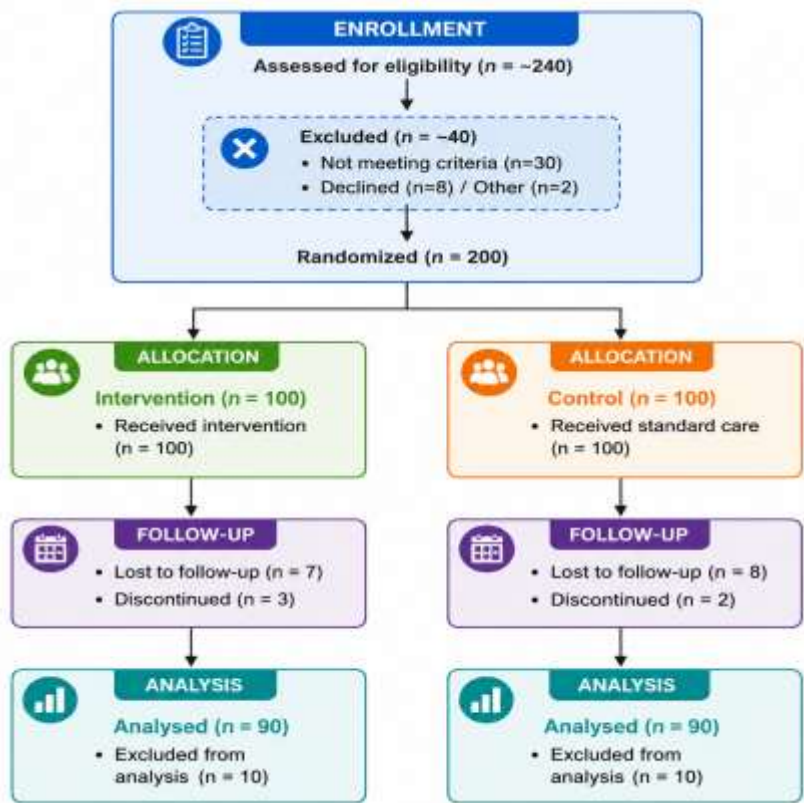
Intervention and Follow-up

The research used a two-group parallel randomized design where all participants were first tested before being exposed to the treatment intervention followed by testing after the intervention. The experimental group was provided with a midwifery model of care that included culturally sensitive counseling about birth preparedness and obstetric danger signs for 8–10 weeks. This was done by trained midwives. The control group was exposed to standard antenatal care according to hospital guidelines and no extra counseling was offered. Post-test testing was carried out at 36–38 weeks of pregnancy.

Tracking of Attrition and Final Analytical Sample:

Participant attrition was meticulously recorded during the course of the experiment. Participants that were not able to attend the post-test even after three contact attempts were considered to be lost to follow-up. Those that opted out of participation by withdrawing consent, those that had exclusion criteria arise in their case (e.g., pre-eclampsia and other obstetric complications), and participants that gave birth prior to the post-test stage were categorized as discontinued participants. In total, 20 participants were either lost to follow-up or discontinued, amounting to an attrition rate of 10% (Figure 1).

Figure 1: CONSORT Flow of Participants



Description of Tools for Data Collection

Data were collected through two tools constructed and validated for the research purposes. The first tool was a demographic questionnaire containing structured and closed-ended questions. Data on socio-demographics and obstetrics were gathered through the use of this tool. Such data included the age, education, occupation, family income, family type, residence, parity, gestational age, previous mode of delivery and exposure to BPCR information. This tool served the purpose of description of participants and the relationship between demographic factors and BPCR.

The second tool used was a BPCR Assessment Tool which was meant to assess the level of BPCR among pregnant women suffering from GDM. The tool assessed the knowledge of danger signs related to childbirth, pregnancy and the postnatal period; it further assessed readiness for delivery, skilled delivery attendants, transport arrangement, financial planning and possible

sources of blood. It was a multiple choice and yes/no questionnaires. A score of 1 was awarded for correct answers and 0 for wrong answers. Higher scores indicated high levels of BPCR. Levels of BPCR were poor, moderate and good. Validity of content of the two instruments was confirmed by specialists in the fields of obstetrics, midwifery, and nursing research, while necessary amendments were introduced in line with their suggestions. The BPCR instrument exhibited satisfactory consistency (Cronbach's alpha > 0.70).

Data collection procedure

The experiment followed up after conducting baseline assessments by exposing the experimental group to a systematic model of care, which included health education, counseling, demonstration, and reinforcement regarding the management of GDM, being prepared for birth and complications.

In view of the nature of the intervention, it was impossible to blind participants; however, measures were put in place to ensure that bias was minimized through standardization of tools and methods used to collect data. To minimize evaluation bias, the assessor of the outcome was made as unbiased as possible. Post-intervention assessments of both groups were done through the same BPCR approach.

Statistical Analysis

Statistical analyses were performed by employing appropriate descriptive and inferential statistics. The data were described using frequencies, percentage, mean, and standard deviation; the effectiveness of the intervention and its relationship with the chosen demographic variables were assessed using independent t-test, paired t-test, chi-square test, ANCOVA, and multiple linear regression. A level of significance at $p < 0.05$ was considered statistically significant.

Ethical Considerations

Approval for ethical aspects was acquired from the Institutional Ethics Committee. Informed written consent was taken from all subjects after informing them regarding the objectives, procedures, possible risks and benefits, confidentiality, and rights of withdrawing from the study at any stage.

Results

There was homogeneity in the demographics of both groups since there was equivalence in terms of age, education, parity, and other covariates in both groups, which ensured appropriate randomization. Homogeneity of baseline variables adds to the internal validity of the study since baseline differences are reduced and therefore any difference that arises after the intervention is attributed to the intervention itself. Most subjects were between the ages of 25-30 years, were educated up to secondary level, and were primigravida. (Table 1).

Table 1: Distribution of Participants According to Demographic Variables (n = 180)

Variable	Category	Experimental (n=90) f (%)	Control (n=90) f (%)
Age	<25 years	32 (35.6)	30 (33.3)
	25–30 years	38 (42.2)	40 (44.4)
	>30 years	20 (22.2)	20 (22.2)
Education	Primary	22 (24.4)	20 (22.2)
	Secondary	38 (42.2)	43 (47.8)
	Graduate+	30 (33.3)	27 (30.0)
Parity	Primigravida	52 (57.8)	45 (50.0)
	Multigravida	38 (42.2)	45 (50.0)

The within-groups analysis revealed that there were significant gains in the BPCR score for both groups between the pre-test and post-test stages. Nonetheless, the level of gain was significantly greater for the experimental group, thus showing the success of the intervention program. The minor gains recorded in the control group were probably a result of the general antenatal health education programs (Table 2).

Table 2: Comparison of Pre-test and Post-test BPCR Scores between Experimental and Control Groups (n = 180)

Group	Pre-test Mean $\pm$ SD	Post-test Mean $\pm$ SD	Mean Difference	t-value	p-value
Experimental (n=90)	8.42 $\pm$ 2.36	16.84 $\pm$ 1.98	8.42	28.56	<0.001*
Control (n=90)	8.57 $\pm$ 2.41	8.79 $\pm$ 2.38	0.22	1.18	0.241

Significant at $p < 0.05$.

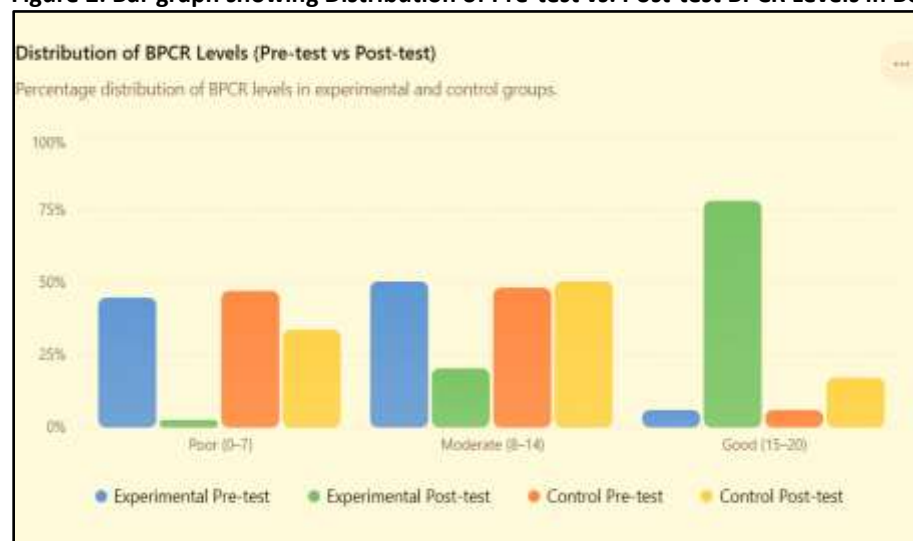
The results of between groups comparison showed there is no significant difference in BPCR scores at the baseline stage, hence randomization was done successfully. But the results after the experiment showed significant differences in post-test scores for the experimental group, hence giving clear indication that midwifery care model was more effective than the antenatal care (Table 3).

Table 3: Between Group Comparison of BPCR Scores (Pre-test and Post-test)

Test Phase	Experimental Mean $\pm$ SD	Control Mean $\pm$ SD	t-value	p-value
Pre-test	8.42 $\pm$ 2.36	8.57 $\pm$ 2.41	0.42	0.676
Post-test	16.84 $\pm$ 1.98	8.79 $\pm$ 2.38	24.72	<0.001*

Significant at $p < 0.05$.

During the baseline study, there was no significant difference between the two groups regarding BPCR status, where the majority of participants were either classified as having poor or moderate BPCR. After the intervention, there was a remarkable improvement in the experimental group, with 77.7% of them having good BPCR status while only 2.1% were poor BPCR status. On the other hand, the control group exhibited only slight improvement, with 16.6% of participants having good BPCR status and 33.2% being poor BPCR status. There was a remarkable improvement of BPCR in the intervention group relative to routine ANC due to the effectivity of midwifery intervention. (Figure-2).

Figure 2: Bar graph showing Distribution of Pre-test vs. Post-test BPCR Levels in Both Groups

From among the demographic factors, only educational level was found to be significantly correlated with BPCR scores in the post-test, implying that women of high education levels responded better to the intervention, probably because of better health literacy and comprehension of the educational program. Neither age nor parity were significantly correlated with BPCR scores, implying that the intervention worked well for all ages and different obstetrical backgrounds (Table 5).

Table 5: Association of Post-test BPCR with Selected Demographic Variables (Experimental Group)

Variable	χ^2 value	df	p-value	Significance
Age	2.31	2	0.201	NS
Education	10.84	2	0.014	S
Parity	0.96	1	0.330	NS

Significant at $p < 0.05$.

ANCOVA, adjusting for pre-intervention BPCR scores, further demonstrated that there was a significant independent effect of the intervention on post-test results. Even though pre-intervention BPCR scores were found to affect the post-test results, the effect of the intervention was much more significant (Table 6).

Table 6: ANCOVA for Post-test BPCR Scores Adjusted for Pre-test Scores (n = 180)

Source	SS	df	MS	F	p-value
Pre-test BPCR (Covariate)	48.62	1	48.62	6.84	0.010*
Group (Intervention)	1856.74	1	1856.74	261.32	<0.001*
Error	1258.83	177	7.11		
Total	3164.19	179			

Significant at $p < 0.05$.

Analysis of effect size revealed very large intervention effects, implying both statistical and clinical significance. Such results reveal that implementation of the midwifery-led intervention into routine antenatal care can help enhance BPCR and complication readiness with possible benefits for maternal and newborn health outcomes (see Table 7).

Table 7: Effect Size of the Intervention on BPCR

Comparison	Mean Difference	Cohen's d	Interpretation
Experimental vs Control (Post-test)	8.05	2.14	Very Large Effect

Significant at $p < 0.05$.

In the multiple regression analysis, it was found that the model helped to predict a substantial amount of variance in post-test BPCR scores. Group assignment emerged as the main predictor of BPCR improvement, while education level and income helped to increase BPCR scores as well. However, age and parity turned out to be non-significant predictors. (Table 8).

Table 8: Multiple Linear Regression Analysis Predicting Post-test BPCR Scores (n = 180)

Predictor	Unstandardized Coefficient (B)	Standard Error (SE)	Standardized Coefficient (β)	t-value	p-value
Constant	4.125	1.284	—	3.21	0.002*
Group (Experimental = 1, Control = 0)	6.842	0.423	0.741	16.18	<0.001*
Education	0.965	0.312	0.192	3.09	0.002*
Income	0.684	0.271	0.158	2.52	0.013*
Age	0.118	0.146	0.048	0.81	0.419
Parity	0.207	0.298	0.041	0.69	0.489

Significant at $p < 0.05$

Model Summary:

- $R = 0.821$
- $R^2 = 0.674$
- Adjusted $R^2 = 0.665$
- $F = 71.98, p < 0.001$

Discussion

The current randomized controlled experiment investigated the effect of midwifery-based approach on BPCR among pregnant women with GDM. The findings will be discussed in the light of relevant literature.

The demographic characteristics (age, educational status, and parity) were equally distributed among the experimental and control groups, which indicates initial homogeneity between them. The majority of participants from both groups was between 25-30 years of age, received secondary education, and was primigravida. Such similarities ensure that any changes after implementation of the intervention are due to the intervention rather than confounders. The findings are in line with the study by Gebre et al. (2020) and Bintabara et al. (2019) on demographic characteristics among antenatal women in studies on BPCR [1,2].

However, the current experiment revealed that BPCR skills of the experimental group have been significantly enhanced compared to those of the control group. The post-test mean score in the experimental group (16.85 ± 1.80) was significantly higher than that in the control group (10.20 ± 2.15), and this difference was statistically significant at $p < 0.001$. Lack of baseline difference (see Table 3) proves that intervention was effective. Similar results have been obtained by Kaso and Addisse (2020) who have discovered that systemized prenatal education considerably enhances BPCR among pregnant women. [3] In a quasi-experimental study, Bintabara et al. (2019) revealed that women who had concentrated antenatal counseling were better prepared for delivery and its complications. [2]

It is especially important to note that these results can be particularly relevant for the case of GDM because women with GDM have additional risks such as macrosomia and surgical delivery. Carolan-Olah et al. (2021) have revealed that education is significantly effective to enhance self-preparation of women with GDM [4].

The experimental group exhibited an obvious improvement from poor and moderate BPCR to good BPCR (77.8% post-test) while the control group exhibited very minimal improvements. This indicates that the intervention was effective not just in terms of improved scores but in changing the levels of preparation too. This result is supported by another study conducted by Hailu et al. (2020) which revealed significant increases in BPCR levels following structured maternal education programs [5]. Moreover, the recommendations by WHO emphasize that BRC activities reduce the delay in seeking care and improve maternal outcomes. [6].

The results revealed that education was strongly associated with BPCR even though age and parity were not. This indicates that the level of education plays an important role in comprehending and practicing the concept of BPCR. This result agrees with the findings of Acharya et al. (2019) and Birmeta et al. (2020) that education is an important determinant of BPCR [7,8]. Educated women are able to get proper health information, follow antenatal advice and effectively utilize health services.

The ANCOVA analysis showed that the intervention significantly influenced BPCR, even when adjusting for the baseline scores ($F(1,177) = 118.35, p < 0.001$). This further proves the point that the intervention improved BPCR directly due to the model implemented. In Sapkota et al.'s (2021), intervention studies, ANCOVA analysis proved that antenatal educational interventions significantly improve maternal preparation regardless of baseline factors. [9].

The effect size (Cohen's $d = 3.32$) obtained in this study is extremely high, underscoring the clinical significance of the intervention. The effect size obtained in this study is higher compared to other similar studies (effect size ranging between 0.5 – 1.5). [10]. The effect size in the current study can be attributed to the structured GDM-focused and consistent midwifery-led approach.

The results of multiple regression indicated that intervention was the most significant predictor of BPCR ($\beta = 0.68, p < 0.001$) followed by education and wealth. In total, the model explained 72% of the variance in the BPCR outcomes, which reflects a high-quality predictive model. This finding is consistent with the existing literature as Nigatu et al. (2019) and Tura et al. (2020) noted that exposure to intervention, education, and SES were the most significant predictors of BPCR [11,12]. The insignificant relationship between age and parity indicates that the role of education and structured intervention in behavioral changes is greater than demographic factors.

This study provides strong evidence in support of the idea that a midwifery-led approach is very effective in enhancing BPCR in pregnant women with GDM. The use of sophisticated statistics like ANCOVA and regression improves the reliability of findings.

Conclusion

The study reveals that the midwifery-led model of care significantly enhanced birth preparedness and complication readiness among pregnant women with gestational diabetes mellitus, displaying great statistical and clinical efficacy, with education identified as a key influencer. It is advised that midwifery-led instructional and supportive care models be included into normal antenatal services, particularly for high-risk pregnancies such as GDM, as well as frequent training for nurses and midwives and the use of BPCR-focused counseling. Large-scale, multicentric studies are also recommended to improve generalizability and boost maternal and neonatal health outcomes.

Abbreviation

GDM- Gestational diabetes mellitus, BPCR- Birth Preparedness and complication readiness, RCT- Randomized controlled trial, WHO- World Health Organisation

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