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The effect of SARS-CoV-2 infection on maternal, fetal and neonatal outcomes: A single-centre case series in Western India

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ABSTRACT

Objectives: To study the effect of SARS-CoV-2 Infection on maternal, fetal and neonatal outcomes.
Materials and Methods: A retrospective cohort study was undertaken in a tertiary Covid Care Centre (CCC), Ahmedabad, Gujarat, India. The study was conducted from 1st April 2021 to 30th June 2021. A total of 22 symptomatic antenatal patients diagnosed with SARS-CoV-2 by RT-PCR method were included.
Results: The mean age of the mothers was 30.2 ± 4.0 years and the mean gestational age was 29.7 ± 9.1 weeks. Six (27.3%) patients required intensive care unit (ICU) admission. 63.7% of the subjects required respiratory support i.e. 40.9% with nasal oxygen therapy and 22.7% with invasive ventilation. Six Intrauterine fetal death were also recorded. Only two neonates (born at 37 and 38 weeks of gestation, respectively) both with low Apgar scores at 1st minute & 5th minute experienced respiratory distress and required neonatal ICU (NICU) admission. Among them, only one neonatal death was recorded because of the diffuse exudative lesions & lung whiteout. The current study had the maternal mortality rate of 13.6% (3/22) owing to various medical complications with two of them succumbing to multiple organ failure with Disseminated intravascular coagulation (DIC) & one patient to sepsis with DIC.
Conclusion: The clinical course of COVID-19 during pregnancy appears to be unique to each patient, with a higher incidence of DIC and multiorgan failure. Hence, a multidisciplinary team approach is vital in individualising the timing, mode for delivery, and course of management in these patients.

1. Introduction

It is not the first time that Zoonotic virus have led to worrisome situations all over the world. At two separate occasions, the Severe Acute Respiratory Syndrome (SARS) in 2003 followed by Middle East respiratory syndrome (MERS) in 2012 resulted in case fatality rate (CFR) of 10.5% and 34.4% respectively.[1,2] At the time of writing, COVID-19 with the global cumulative incidence of 185, 786, 411 reported cases and 4, 019, 859 associated deaths with a CFR of 2.2% has already caused more deaths than MERS and SARS combined.[3] An insight from the past has taught us to evolve continuously on every front to prevent mortality in highly vulnerable community from these infections. This brings us to the cohort scrutinized thoroughly in this study i.e. pregnant women who are

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regarded as one of the highly vulnerable groups to this respiratory syndrome. As the physiological changes in pregnant subjects go hand-in-hand over different trimesters, it makes them more prone to respiratory infections that ultimately progress to respiratory failure.

Since the beginning of this pandemic, several studies have shed light on the genetic, virologic, epidemiologic and clinical aspects of this emerging infection. Leaving aside the significant heterogeneity in reported studies, contradictory observations have been reported in terms of adverse effects on mother as well as on newborns, causing fetal distress, premature labor, respiratory distress, thrombocytopenia accompanied by abnormal liver function, and even death.[4–7] Moreover, lack of clarity on the route of infection in SARS-Cov-2-positive neonates as well as conflicting evidence from nucleic acid-based testing and antibody testing,[8,9] in neonates born to mothers with COVID-19 has raised further eyebrows among treating obstetricians. But, due to variation in demographics, treatment protocol and logistical resources, realization on neonatal outcomes following maternal COVID-19 in pregnancy is still based on case series and centre experiences. Hence, we too as a part of medical fraternity felt the need to study the effect of SARS-CoV-2 infection on maternal, fetal and neonatal outcomes in order to formulate better management plans for the future. Our study is not a typical case control analysis as it studies the retrospectively collected data of antenatal patients diagnosed with SARS-CoV-2. Ultimately, every individual must co-ordinate, co-operate, collaborate and innovate to reduce the morbidity and mortality in this pandemic.

2. Materials and Methods

2.1. Study design

A retrospective cohort study was undertaken among the pregnant women with confirmed or suspected SARS-CoV-2 infection who were admitted/referred to a tertiary Covid Care Centre (CCC), Ahmedabad, Gujarat over a span of three months starting from 1st April 2021 to 30th June 2021.

Patients with following inclusion criteria were enrolled in the study:

1. All symptomatic antenatal patients diagnosed with SARS-CoV-2 by RT-PCR method.
2. Patient with written informed consent signed by patient/guardian.

Following mothers were excluded from study:

1. Any pregnant patient diagnosed with SARS-CoV-2 and delivered outside the study centre.
2. Any asymptomatic pregnant patient diagnosed with SARS-CoV-2.

RT-PCR test being highly specific is the current gold standard diagnostic method for the diagnosis of COVID-19. Only Indian Council of Medical Research (ICMR) approved kits were used for the detection of the SARS-CoV2. On admission, the nasopharyngeal and oropharyngeal swabs of patients were taken and sent for RT-PCR. Detection was based on RT-PCR method targeting the RNA-dependent RNA polymerase (RdRp) gene. HRCT thorax scan examination was carried out in selective patients (only mothers). Chest X-ray of selective neonates (case specific) were take. Clinical manifestations such as fever, coughing, myalgia, fatigue, headache, diarrhoea or dyspnea were recorded.

2.2. Data collection & analysis

The data was collected using a predesigned template which was filled by the concerned physician involved in the immediate treatment of the patient. During clinical course, personal interview was held with each subject. Interview method has been considered to be more appropriate as it provides an opportunity to the interviewer to be able to extract the appropriate information by coming in face to face contact with the subject. Follow up data were retrieved from digital and written patient records. In a few cases where follow-up data were not available from hospital records, the patient or their general practitioner was called to obtain information on their condition, hospital admissions and discharge summary. All care and caution were exercised while utilizing the patient data for current research as outlined in the hospital guidelines pertaining to the usage of patient's data for this study and confidentiality was maintained throughout. The collected data variables obtained was compiled by using an excel spreadsheet. The outcome data was descriptively analysed. The baseline patient characteristics are presented as frequencies & percentage for the categorical variables and as the means and standard deviations for continuous variables. After appropriate data filtration, the data sheet was transferred and analyzed using Statistical Package for Social Sciences (SPSS vs. 22.0).

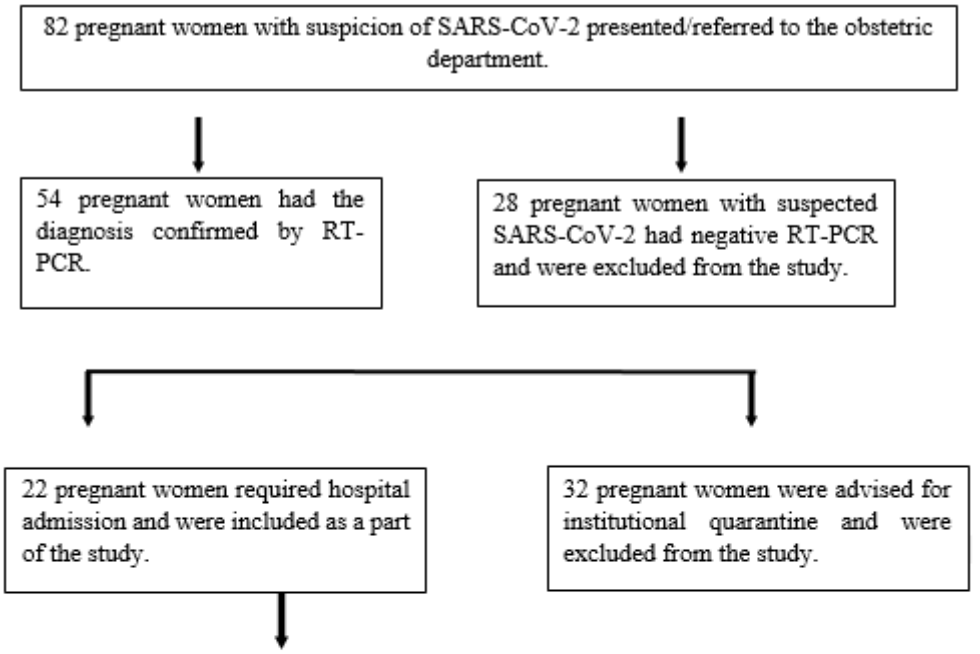
2.3. Subject confidentiality & consent

Confidentiality was maintained regarding patient specific data and it was kept in strict confidence. Ethical committee approval was sought.

3. Results

We studied 22 COVID-positive (RT-PCR) mothers over a span of 3 months who were admitted in the dedicated COVID ward/ICU in accordance with the inclusion−exclusion criteria.

Table 1 depicts the demographic details as well as baseline characteristics of the pregnant patients at



Outcomes of interest	
Maternal Outcome	**Neonatal Outcome**
Symptoms on presentation	Birth weight
Preterm delivery (PTD)	APGAR scores at 1 and 5 minutes
Mode of delivery	Neonatal intensive care unit (NICU) admission
Course of treatment	Neonatal investigations for COVID-19
Need for respiratory support	IUD / Post-delivery death / Discharge
Maternal mortality rate / Discharge	

Diagram 1: Flowchart of the study

presentation. The mean age of the mothers was 30.2 ± 4.0 years (range 23–37 years) and the mean gestational age was 29.7 ± 9.1 weeks. 15 (68.2%) patients had none of the comorbidities while 3 (13.6%) had obesity, 2 (9.1%) patients each with hypothyroidism and diabetes mellitus were also recorded. One patient each with Juvenile Myoclonic Jerks, Epilepsy, pregnancy induced DM and Pregnancy induced HTN respectively. On admission, the main complaint was malaise in 17 (77.3%), followed by fever in 16 (72.7%), dry cough in 5 (22.7%), headache in 4 (18.2%), diarrhoea in 3 (13.6%) and sore throat in 2 (9.1%) patients. 77.3% of the women enrolled were in the third trimester followed by first (13.6%) & second trimester (9.1%). 8 (36.4%) patients had mild while 9 (40.9%) and 5 (22.7%) had moderate and severe severity of the disease respectively.

Table 2 demonstrates the radiological investigation. Pulmonary CT scan on admission was carried out for all 22 cases. Following CT signs were evaluated for each patient: Location: a) Peripheral, b) Intermediate, c) Subpleural; Density: a) Ground-glass opacity; Lung Lobe involvement: a) Single lobe, b) Bilateral / Multiple lobes. Among them 14 (63.6%) patients were normal, while remaining 36.4% cases were found abnormal in different degrees including ground-glass opacity (GGO), patch-like shadows mostly affecting the multiple lobes.

Table 3 demonstrates the need of respiratory support. 63.6% of the subjects required respiratory support in

Table 1: Baseline characteristics of the pregnant patients at presentation.(n=22)

Maternal Age group (Years)	
20 – 25 Years	2 (9.1%)
26 – 29 Years	7 (31.8%)
30 – 35 Years	11 (50%)
36 – 39 Years	2 (9.1%)
Comorbidities	
Obesity	3 (13.6%)
Hypothyroidism	2 (9.1%)
Diabetes Mellitus	2 (9.1%)
Pregnancy induced DM	1 (4.6%)
Pregnancy induced HTN	1 (4.6%)
Juvenile Myoclonic Jerks	1 (4.6%)
Epilepsy	1 (4.6%)
None	15 (68.2%)
Pregnancy trimester at diagnosis	
First	3 (13.6%)
Second	2 (9.1%)
Third	17 (77.3%)
Symptoms on presentation	
Fever	16 (72.7%)
Dry Cough	5 (22.7%)
Sore throat	2 (9.1%)
Malaise	17 (77.3%)
Headache	4 (18.2%)
Diarrhoea	3 (13.6%)
COVID-19 severity	
Mild	8 (36.4%)
Moderate	9 (40.9%)
Severe	5 (22.7%)

Table 2: Chest-CT manifestations (n=22)

Location	
Peripheral	6 (27.3%)
Intermediate	3 (13.6%)
Subpleural	5 (22.7%)
Density	
Ground-glass opacity	6 (27.3%)
Normal	16 (72.7%)
Lung Lobe involvement	
Single lobe	2 (9.1%)
Bilateral / Multiple lobe	6 (27.3%)
Normal characteristics	15 (68.2%)

one way or other i.e. 40.9% with nasal oxygen therapy and remaining 22.7% with invasive ventilation. 8 (36.4%) patients required no respiratory support.

Table 3: Respiratory support (n=22)

Nasal oxygen therapy	9 (40.9%)
Invasive mechanical ventilation	5 (22.7%)
Not required	8 (36.4%)

Tables 4 and 5 depicts the mode of delivery in pregnant patients presenting in third trimester and the indications of delivery respectively. More than half of the patients (64%) required a cesarean section (CS) for obstetrics indications (seven for maternal distress, one each for obstructed labor and severe oligohydramnios respectively), and the rest of the patients (36%) delivered vaginally. Out of five patients who delivered normally, none required instrumental delivery.

Table 4: Route of delivery

Vaginal delivery	5 (22.7%)
Cesarean section[a]	9 (40.9%)

a -includes one twin pregnancy.

Table 5: Indications for delivery (n=14)

Maternal Distress	7 (50%)
Obstructed labor	1 (7.1%)
Oligohydramnios	3 (21.5%)
Early onset of labor	1 (7.1%)
Intrauterine fetal death	2 (14.3%)

Table 6 shows the incidence of anaesthesia used in C-section. All the nine patients who got delivered through CS were administered spinal anaesthesia.

Table 6: Anaesthesia used for CS (n=9)

General	0
Spinal	9 (100%)

Tables 7 and 8 demonstrates the type of intervention and details about the medical management used during the course of the treatment respectively. 12 (54.5%) patients required only medical intervention while remaining 10 (45.5%) required both medical & surgical intervention.

Table 7: Intervention (n=22)

Medical intervention	12 (54.5%)
Medical & Surgical intervention	10 (45.5%)

Table 8: Medical management

Remdesivir	13 (59.1%)
Fabiflu	3 (13.6%)
Zinc	21 (95.4%)
Antibiotic	22 (100%)
Steroids	19 (86.4%)

Tables 9 and 10 depicts the obstetric & medical complications and final maternal outcome respectively. The current study had the maternal mortality rate of 13.6% (3/22) owing to various medical complications with two of them succumbing to multiple organ failure with Disseminated intravascular coagulation (DIC) & one patient to sepsis with DIC. The patient with Postpartum

Haemorrhage (PPH) responded to the treatment and got discharged.

Table 9: Obstetric & medical complications

Disseminated intravascular coagulation (DIC)	3 (13.6%)
Postpartum haemorrhage (PPH)	1 (4.6%)
Multiple organ failure (MOF)	2 (9.1%)
Sepsis	1 (4.6%)
None	19 (86.4%)

Table 10: Final outcome (Maternal; n=22)

Discharged	19 (86.4%)
Death	3 (13.6%)

Table 11 depicts the neonatal outcome. The Apgar score (measured at two separate time intervals i.e., at 1^{st} minute and at 5^{th} minute) was normal in 8 (80%) babies. The mean Apgar score at 1^{st} minute and at 5^{th} minute was 7.1 ± 1.9 and 8.6 ± 2.1 respectively. Both the babies bearing low Apgar scores required NICU admission. Among them, one neonate was discharged well with a good outcome. Only one neonatal death was recorded because of the diffuse exudative lesions & lung whiteout. Six Intrauterine fetal death were also recorded in this study.

Table 11: Neonatal outcome

NICU admission required (n=16)	2 (12.5%)
Discharged (n=16)	9 (56.3%)
Premature delivery (n=16)	0
Neonatal death (n=16)	1 (6.3%)
Intrauterine fetal death (n=22)	6 (27.3%)
Apgar 1st minute (n=10)	7.1 ± 1.9
Apgar 5th minute (n=10)	8.6 ± 2.1
Fetal Respiration rate (n=10)	21.9 ± 7.9
Fetal Heart rate (n=10)	135.8 ± 7.7
Birth Weight (n=10)	2.638 ± 0.4 kg

Table 12 shows the other characteristics of the patients which were recorded during the course of the treatment. The baseline patient characteristics are presented as mean and standard deviation for continuous variables.

Table 12: Other characteristics

Mean gestational age at diagnosis (weeks)	29.7 ± 9.1
Mean gestational age of delivered mothers (weeks)	34.8 ± 3.6
Length of hospital stay (days)	6.8 ± 5.6
Body Mass Index (BMI)	25.8 ± 2.6
Pulse	92.4 ± 19.5
Systolic Blood Pressure (SBP)	119.3 ± 9.2
Diastolic Blood Pressure (DBP)	78.29 ± 8.6
Glasgow Coma Score (GCS)	15 ± 0
Ferritin	245.9 ± 179.9
C-reactive protein	64.6 ± 56.8
D-dimer	2830.9 ± 3929.4

4. Discussion

Evaluating the implications of COVID-19 on maternal and neonatal outcome becomes more relevant when we look back in the time of the outbreak caused by coronaviruses at two separate instances. In the year 2003, high maternal mortality during the first trimester and intrauterine growth restriction in the second and third trimesters was recorded at the time of SARS-CoV-1 outbreak.[17] This was followed by an another similar viral outbreak in the year 2012, termed as MERS-CoV infection in which a case series of 11 patients reported the CFR of 35% for pregnant women and 27% for infants.[18] A study by WHO comprising of 25 national and international experts travelled to the affected parts of China in 2020 and investigated 147 pregnant women (64 confirmed, 82 suspected, and 1 asymptomatic with COVID-19) concluded that pregnant women were not at higher risk for developing severe disease due to COVID-19.[19] However, preliminary data of several studies from different countries had demonstrated fluctuating course of the disease from asymptomatic or mild symptoms to maternal death. Moreover, insights from the past pertaining to human coronavirus outbreaks suggests that pregnant women and their fetuses are particularly susceptible to poor outcomes. Hence, our study on 22 pregnant women with confirmed COVID-19 diagnosis was undertaken in order to draw conclusion about any maternal and neonatal consequences that needs our immediate attention and we tried to compare our results with the similar kind of published studies on national as well as on international front. The mean age of the mothers was 30.2 ± 4.0 years and the mean gestational age was 29.7 ± 9.1 weeks. Average body mass index (BMI) was 25.8 ± 2.6 kg/m^2. Fever, dry cough, sore throat, malaise, sore throat, and occasional diarrhoea were the common presenting symptoms. Studies by Yang et al and Guan et al in 2020 reported that individuals with co-morbid diseases are more susceptible to COVID-19.[20,21] Approximately one- third of confirmed cases in the present study had co-morbid diseases (31.8%) and is consistent with the literature. Comparison of maternal baseline characteristics between several published studies has been depicted in Table 13.[10–14]

COVID-19 pneumonia in pregnant patients warrants special consideration as CT radiation is a factor in fetal teratogenicity. Chest CT was performed in approximately one-quarter (27.3%) of the confirmed cases in the present study and more than half of them had findings consistent with COVID-19 infection indicating radiologic imaging might be useful in appropriately selected cases. Also, lymphocytopenia and neutrophilia were the other findings in the present study. The timing and choice of delivery is also

Table 13: Comparison of maternal baseline characteristics

Study	N	Country	Type	Maternal Age (years)	Gestational Age on admission (weeks)
Wu et al (2020)[10]	23	China	Case series	21–37	6–40
Chen et al(2020)[11]	4	China	Case report	23-34	37-39
Liu et al (2020)[12]	15	China	Case series	23–40	12–38
Kapadia SN et al. (2021)[13]	50	India	Prospective	19-36	38.3
Iqbal (2020)[14]	1	USA	Case report	34	39
Present study (2021)	22	India	Case series	23-37	29.7

Table 14: Compares the pregnancy outcomes of women with COVID-19 in different studies

Study	N	Country	Type	Total number of deliveries	Antenatal patients	Delivery by cesarean section	Vaginal delivery	Maternal mortality	Neonatal mortality	Intrauterine fetal death
Liu et al (2020)[15]	15	China	Case series	11	4	10	1	0	0	0
Kapadia SN et al (2021)[13]	50	India	Prospective	50	0	26	24	0	1	0
Liu et al (2020)[15]	16	China	Case series	6	10	6	0	0	0	0
Zhang et al (2020)[16]	16	China	Case series	16	0	16	0	0	0	0
Present study (2021)	22	India	Case series	14	8	9[a]	5	3	1	6

the dilemma among pregnant women with COVID infection but the real onus is on the health professionals to formulate an individualised delivery plan depending on the weeks of gestation and maternal and fetal conditions. Generally, vaginal delivery is the first choice to avoid any risks of major surgery. Septic shock or fetal distress should prompt emergency cesarean delivery. In the present study, 64% required a cesarean section (CS) under spinal anesthesia for obstetrics indications while the rest of the five patients (36%) delivered vaginally. We found a higher operative delivery rate in this study group owing to obstetrics indications (seven for maternal distress, one each for obstructed labor and severe oligohydramnios respectively) and not because of COVID-19. A poorer neonatal outcome in pregnancy and higher rate of the CS with COVID-19 was reported in a systematic review and meta-analysis published by Mascio et al.[22]

A total of 10 neonates (including one set of twins) were born with median gestational age at birth being 37 weeks. As COVID-19 presents as an acute infection, if developed close to delivery it is unlikely to have an impact on birth weight and mean birth weight in the current study was 2,638 grams. Most of the neonates were asymptomatic and had no signs of SARS-CoV-2 infection confirmed by nasopharyngeal swab testing on day 1 and repeated on day 3. Isolation is the key to prevent infection transmission to neonates and thus majority of neonates are isolated in NICU to closely monitor their condition. Only two neonates (born at 37 and 38 weeks of gestation, respectively) both with low Apgar scores at 1^{st} minute & 5^{th} minute experienced respiratory distress and required neonatal ICU (NICU) admission. One neonate from NICU was discharged with a good outcome. Only one neonatal death was recorded throughout the study because of the diffuse exudative lesions & lung whiteout (Figure 1). Six intrauterine fetal deaths were also recorded owing to obstetrics reasons. In terms of maternal mortality; hypertensive disorders of pregnancy, obstructed labor, complications of induced abortion, haemorrhage and sepsis are the leading severe obstetric complications in developing countries. The current study had the maternal mortality rate of 13.6% (3/22) owing to various medical complications with two of them succumbing to multiple organ failure & one woman to sepsis. In lieu of these findings, maternal mortality cannot be ruled out with COVID-19 infection during pregnancy. Table 14 compares the pregnancy outcomes of women with COVID-19 in different studies.[15,16]

As with the majority of case series, the design of the current study is also subject to limitations, and findings of this study have to be seen in light of some of the factors. The nature of the study is retrospective, single-institution study with limited time frame and with small sample size. So caution must be employed while extrapolating this data to cohorts of other countries. However, single-centre studies with homogeneous populations and standard care processes, offers the advantage over multicentre studies that differs in the availability of their logistical resources and lack of uniformity in patient management. The another limitation of the study was the lack of statistics pertaining to the final outcome data of the pregnant women who had not delivered

by the end of the study period.

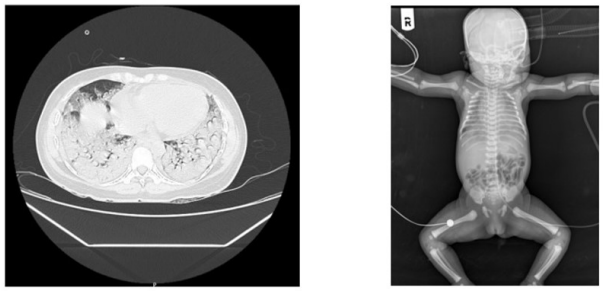


Fig. 1: 26-year-old pregnant woman with gestational age of 38 weeks presented with fever, dry cough and malaise underwent CT scan examination. (**a**) Coronal chest CT image of mother obtained just before delivery shows bilateral extensive ground-glass opacities (GGOs) with crazy wave pattern in both lungs. (**b**) Chest X-ray image at birth of the vaginally delivered baby girl (APGAR score of 3 & 4 at 1st min and 5th min respectively.) shows white-out lung, a complication due to maternal respiratory distress during labor

5. Conclusion

The world is battling with SARS Cov-2 infection for the past 1.5 years only. This relatively new virus with its ever-emerging mutations has baffled the medical fraternity. Even though multiple studies have been published on COVID-19 in pregnancy, there are still many unanswered questions. The clinical course of COVID-19 during pregnancy appears to be unique to each patient, with a higher incidence of DIC and multiorgan failure leading to maternal mortality. Hence, it isn't easy to generalize a treatment algorithm as coronavirus affects almost all the body organs. A multidisciplinary team approach is vital in individualizing the timing, mode for delivery, and course of management in these patients.

6. Source of Funding

None.

7. Conflict of Interest

None.

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