

Evaluation of Clinical Profile, Anthropometric Measurements and Biochemical Parameters in Obesity Associated Type 2 Diabetes: A Hospital Based Study

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Conflict of interest: Nil

Abstract

Background: Obesity associated Diabetes Mellitus (DM), also known as Diabetes, refers to the coexistence of obesity with DM.

Aim: The aim of the present study is to evaluate the various clinical profile, anthropometric measurements and biochemical parameters of obesity associated type 2 diabetes mellitus vis-à-vis obese non-diabetes mellitus and healthy controls.

Materials and Methods: This is a case control study conducted among the patients of Obese DM and Obese non-DM patients of Barpeta and surrounding areas and attending the Medicine Department of Fakhruddin Ali Ahmed Medical College and Hospital and study was conducted for a period of one year w.e.f 10th September, 2021 to 9th September 2022. Total number of 20 cases of Obese type2 Diabetic of 18 to 40 years age attending the Department of Medicine were screened and that fulfil the inclusion and exclusion criteria were included. 20 number of age-matched, unrelated, healthy controls (n=20) were also included in the study. The investigations done were: Fasting blood glucose, HbA1C, Fasting Insulin, Fasting lipid profile including Total Cholesterol, HDL-cholesterol, LDL-Cholesterol, Triglycerides, complete hemogram, serum creatinine and TSH. The statistical analysis was carried out in SPSS software (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

Results & Discussion: In the current study, the mean age of Obese-Non Diabetes was found to be 29.38±4.47 while the mean age of Obese- Diabetes subjects was found to be 37.60±4.808 which suggested that the prevalence of the disease in middle adulthood period of life. Further, sedentary life style, frequent consumption of food and lack of exercise are the most important risk factors contributing to the development of Obese-diabetes. The HOMA-IR values were higher in obese-diabetes mellitus (4.495±2.324) as compared to obese-non-diabetic patients (2.49±0.621) and healthy controls (1.65±0.513). It was found that in the HOMA-IR values were significant in obese-diabetic subjects compared to healthy controls (p=0.078). An increased serum total cholesterol and triglyceride level and decreased HDL cholesterol level in Obese-diabetic compared to healthy control vis-a-vis Obese non-diabetic although not statistically significant. The serum cholesterol levels in healthy controls, Obese-NDM and Obese-DM was found to be 194.05±53.141, 197.2±35.952 and 201.00±46.004 mg/dl respectively. The serum LDL-C levels in healthy controls, Obese-NDM and Obese-DM was found to be 108.55±22.97, 121.80±26.49 and 103.20±24.40 mg/dl. Further, the serum HDL-C level of healthy controls, Obese-NDM and Obese-DM was

found to be 40.55 ± 7.776 , 38.45 ± 9.659 and 36.85 ± 7.256 mg/dl respectively. Lastly, the serum TG level of healthy controls, Obese-NDM and Obese-DM was found to be 181.35 ± 83.42 , 197.65 ± 76.50 and 210.95 ± 83.84 mg/dl respectively.

Conclusion: Various biochemical alterations depicts the picture of underlying metabolic derangements which has been linked with the pathogenesis of obesity associated T2DM. Further studies with larger sample size are required to confirm whether this association is actually prevalent in the population of Barpeta district of Assam.

Keywords: Obesity Associated T2DM, HOMA-IR, Anthropometric Measurements.

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Introduction

Obesity associated DM is also known as Diabesity. It refers to the coexistence of obesity with DM [1]. T2DM is very frequently found in obese patients [2]. In fact it is known that about 86% of people with T2DM are overweight or obese [3] and by 2025, more than 300 million of people will have T2DM associated with obesity [4]. These are mostly due to the excessive adipose tissue and fat redistribution in obese patients, which is directly implicated with hyperglycaemia, hyperlipidaemia, insulin resistance, endothelial dysfunction, and chronic inflammation [5].

Central obesity and other metabolic parameters like elevated plasma glucose, insulin, total plasma concentration and triglycerides, and decreased high density lipoprotein cholesterol concentration are more important than the total obesity [6,7]. The reason for increased risk for abnormal metabolism in people with central obesity is not clearly defined.

The aim of the present study is to evaluate the various clinical profile, anthropometric measurements and biochemical parameters of obesity associated type 2 diabetes mellitus vis-à-vis obese non-diabetes mellitus and healthy controls.

Materials and Methods

This is a case control study conducted among the patients of Obese diabetic and Obese non-diabetic patients of Barpeta and surrounding

areas and attending the Medicine Department of Fakhruddin Ali Ahmed Medical College and Hospital and study was conducted for a period of one year w.e.f 10th September, 2021 to 9th September 2022. Total number of 20 cases of Obese type2 Diabetic of 18 to 40 years age attending the Department of Medicine were screened and that fulfil the inclusion and exclusion criteria were included. 20 number of age-matched, unrelated, healthy controls (n=20) were also included in the study.

Collection of blood samples

After an overnight fast (minimum 8 hours), a total of about 5ml blood (3 ml in clot activator vial and 2 ml in EDTA vial) was collected from the antecubital vein under proper aseptic and antiseptic measures from participants/cases with sterile disposable syringe and needle by venepuncture. The vial was labelled properly with the patient I.D. number and Sample I.D. number. The respective vials, except the EDTA vials were allowed to stand for 20-25 minutes at room temperature and then were centrifuged at 3500 rpm for 10 minutes to separate serum and plasma respectively. Precautionary measures were taken to prevent haemolysis of the samples. The supernatant serum and plasma were used for the investigations.

The EDTA vials were subjected to up and down movement for the blood to be mixed appropriately. Estimation of parameters was

done within 24 hours of collection. The whole blood was used for HbA1c estimation.

The investigations done were: Fasting blood glucose, HbA1C, Fasting Insulin, Fasting lipid profile including Total Cholesterol, HDL-cholesterol, LDL-Cholesterol and Triglycerides were investigated during the study. Other relevant investigations which were taken for correlation including complete hemogram, serum creatinine and TSH.

Ethical clearance was taken from the Institutional Ethics Committee of Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta. All the data were collected with written consent from the volunteers. Anonymity and confidentiality was maintained throughout the study.

Blood glucose: Blood glucose was estimated by VIROS GLU slide method was performed using the VITROS GLU slides in the VITROS 5600 integrated and fully automated chemistry analyzer.

Estimation of Total cholesterol: The VITROS CHOL slide method was performed using the VITROS CHOL slides in the VITROS 5600 integrated and fully automated chemistry analyzer.

Estimation of direct HDL (dHDL): The VITROS dHDL slide method was performed using the VITROS dHDL slides in the VITROS 5600 integrated and fully automated chemistry analyzer.

Estimation of Triglyceride: The VITROS TRIG slide method was performed using the VITROS TRIG slides in the VITROS 5600 integrated and fully automated chemistry analyzer.

Estimation of LDL: LDL cholesterol was not directly measured. It was calculated by the formula proposed by Friedewald which is mentioned below.

$$\text{LDL-c} = \text{TC} - [\text{HDL-c} + \text{TG}/k], k = 5$$

This formula assumes the triglyceride/cholesterol ratio in VLDL to be 5:1. However, it is changeable with serum triglyceride levels, and accepted with triglycerides less than 400 mg/dl.

Estimation of glycated haemoglobin (HbA1c): Hemoglobin A1c was estimated by the D-10 dual mode machine from Bio-Rad Laboratories. It works on the principle of HPLC. It is an automated cation exchange HPLC instrument that is used for quantification of different fractions of hemoglobin.

Estimation of Serum TSH: Serum TSH was estimated using VITROS TSH Reagent pack in VITROS 5600 integrated system. It works by immunometric immunoassay technique.

Estimation of Serum Creatinine: Serum creatinine was estimated using the VITROS CREA Slides in the VITROS 5600 Integrated System.

The statistical analysis was carried out in SPSS software (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Results were expressed as means \pm standard deviations (SD).

Results and discussion

Each enrolled subject were categorised into two sub-cohorts namely;

Obese non-diabetic (n=20) and **Obese diabetic (n=20):** Obese subjects with newly diagnosed type-2 diabetes were taken under the supervision of a senior registered medical practitioner. Few age-matched, unrelated, healthy controls (n=20) were also included in the study. Each enrolled subjects included in the study were interviewed with informed consent about age, gender, date of birth, caste/community, duration of disease, religion, family history of chronic disorder, life style information on food habits, habitual behaviour (smoking and alcohol intake), medication intake, physical activity, clinical

history of associated complications etc. Anthropometric measurements such as height, weight, BMI, waist and hip circumference were also recorded for these subjects. The blood samples (both in EDTA and non-EDTA vials) were prospectively collected from obese-subjects (N=40) who

had visited Department of Medicine, Fakhruddin Ali Ahmed Medical College & Hospital, Barpeta, Assam between 2021-2022. The clinical profile and anthropometric measurements of the enrolled subjects are tabulated in Table 1.1 given below.

Table 1: Clinical and anthropometric parameters of the healthy subjects, obese non-diabetic patients and obese diabetic patients.

| Parameters | Healthy Subjects (n=20) | Obese non-diabetic subjects (n=20) | Obese-diabetic subjects (n=20) |
|---|-------------------------|------------------------------------|--------------------------------|
| Sex, Female | 9 (45%) | 10 (50%) | 11 (55%) |
| Male | 11 (55%) | 10 (50%) | 9 (45%) |
| Education level, Less than high school | 2 (10%) | 2 (10%) | 10 (50%) |
| High School | 6 (30%) | 6 (30%) | 5 (25%) |
| Bachelor Degree or higher | 12 (60%) | 12 (60%) | 5 (25%) |
| Alcohol Consumption Yes | 0 (0%) | 2 (10%) | 0 (0%) |
| No | 20 (100%) | 18 (90%) | 20 (100%) |
| Smoking Never | 12 (60%) | 20 (100%) | 15 (75%) |
| Rare | 7 (35%) | 0 (0%) | 2 (10%) |
| Frequently | 1 (5%) | 0 (0%) | 3 (15%) |
| Junk Food Rarely | 12 (60%) | 8 (40%) | 7 (35%) |
| Frequently | 8 (40%) | 8 (40%) | 11 (55%) |
| Never | 0 (0%) | 4 (20%) | 2 (10%) |
| Physical activity Sedentary | 2 (10%) | 12 (60%) | 6 (30%) |
| Moderate | 0 (0%) | 0 (0%) | 2 (10%) |
| Active | 18 (90%) | 8 (40%) | 12 (60%) |
| Exercise Yes | 8 (40%) | 5 (25%) | 3 (15%) |
| No | 12 (60%) | 15 (75%) | 17 (85%) |
| Co morbidities Yes | 0 (0%) | 15 (75%) | 7 (35%) |
| No | 20 (100%) | 5 (25%) | 13 (65%) |
| Age (years), mean± STD | 28.75±4.43 | 29.38±3.45 | 35.20±4.70 |
| WHR, mean± STD | 0.923±0.036 | 1.056±0.062 | 1.061±0.552 |
| BMI, mean± STD | 22.56±2.45 | 31.99±1.56 | 32.46±2.86 |
| FBS, mean± STD | 84.10±7.96 | 87.65±8.37 | 162.15±57.03 |
| RBS, mean± STD | 112.25±12.25 | 109.05±14.82 | 273.85±87.11 |
| HbA1c, mean± STD | 5.29±0.174 | 5.30±0.243 | 8.71±1.566 |

| | | | |
|-----------------------|---------------|--------------|---------------|
| TSH, mean± STD | 2.179±1.202 | 2.145±0.888 | 3.19±2.678 |
| Cholesterol, mean±STD | 194.05±53.141 | 197.2±35.952 | 201.00±46.004 |
| LDL-C, mean± STD | 108.55±22.97 | 121.80±26.49 | 103.20±24.40 |
| HDLC-C, mean± STD | 40.55±7.776 | 38.45±9.659 | 36.85±7.256 |
| TG, mean± STD | 181.35±83.42 | 197.65±76.50 | 210.95±83.84 |
| HOMA- IR | 1.65 ± 0.513 | 2.49 ±0.621 | 4.495 ± 2.324 |

Case represented as numbers and (% age)

In the current study, the mean age of Obese-Non Diabetes was found to be 29.38±4.47 while the mean age of Obese- Diabetes subjects was found to be 37.60±4.808 which suggested that the prevalence of the disease in middle adulthood period of life. Different observations were noted by Ashraf R *et al.* [8] in their study in the year 2022, where mean age was 47.39 ± 12.61 years of obese-diabetic. In our study, 55% (11 out of 20) diagnosed with Obese-DM were female while 45% (9 out of 20) were males with a female ratio of 1.2: 1. While recent studies [8] indicate that 42.5% (166 of 390) of the cases were males and 57.4% (224 of 390) were females with a male/female ratio of 0.7:1. Further, sedentary life style, frequent consumption of food and lack of exercise are the most important risk factors contributing

to the development of Obese-diabetes. However, all Obese-DM subjects may not have a history of alcohol consumption and smoking.

Determination of Insulin Resistance by HOMA-IR index:

Our findings indicate that the HOMA-IR levels were increasingly higher in obese-diabetic patients compared to healthy controls vis-a-vis obese-non-diabetic patients (Figure 1.2). The HOMA-IR values were higher in obese-diabetes mellitus (4.495±2.324) as compared to obese-non-diabetic patients (2.49±0.621) and healthy controls (1.65±0.513). It was found that in the HOMA-IR values were significant in obese-diabetic subjects compared to healthy controls (p=0.078).

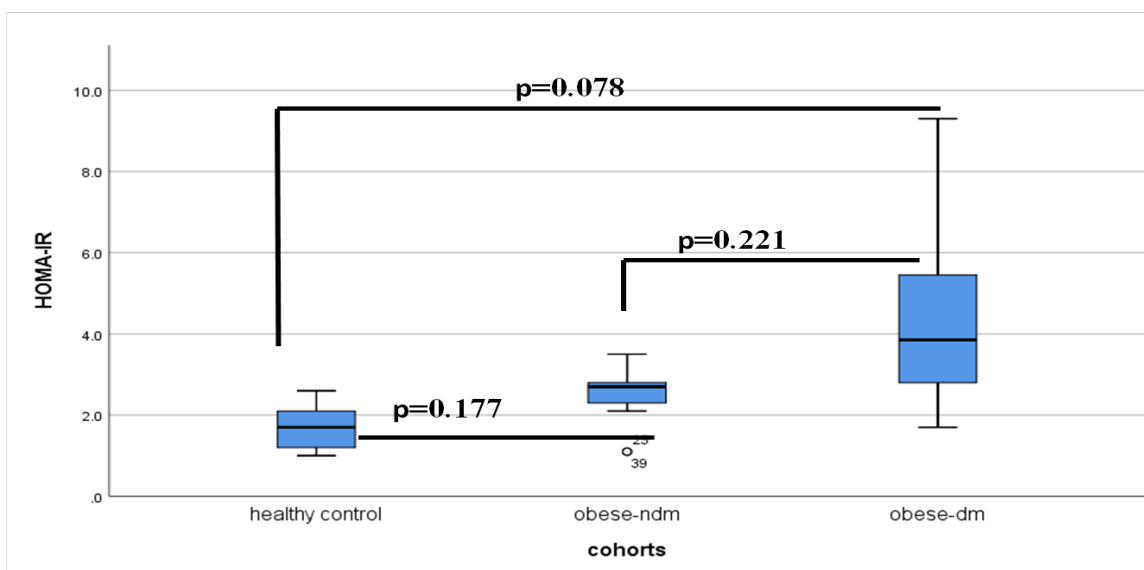


Figure 2: Box-plot analysis showing differences in HOMA-IR levels of Obese diabetes mellitus, Obese-non-diabetes mellitus and Healthy Controls.

Group 1=Healthy Control, Group2= Obese-Non-Diabetes mellitus (Obese-NDM) Cases, Group 3 = Obese- Diabetes mellitus Cases (Obese-DM). The HOMA-IR levels were higher in Obese-DM cases ($p=0.078$) compared to controls. However, the HOMA-IR values were comparative between Obese-non-diabetes mellitus and healthy controls ($p=0.177$) and Obese-NDM and Obese-DM($p=0.221$).

Determination of Serum Fasting Lipid Profile levels by Enzymatic method:

Our findings indicate that there is an increased serum total cholesterol and triglyceride level and decreased HDL cholesterol level in Obese-diabetic compared to healthy control vis-a-vis Obese non-diabetic although not statistically significant (Figure 1.1). Concurrently, statistically non-

significant LDL cholesterol levels was found to higher in Obese non-diabetic than obese-diabetic and healthy controls (Figure 1.1). The serum cholesterol levels in healthy controls, Obese-NDM and Obese-DM was found to be 194.05 ± 53.141 , 197.2 ± 35.952 and 201.00 ± 46.004 mg/dl respectively. The serum LDL-C levels in healthy controls, Obese-NDM and Obese-DM was found to be 108.55 ± 22.97 , 121.80 ± 26.49 and 103.20 ± 24.40 mg/dl. Further, the serum HDL-C level of healthy controls, Obese-NDM and Obese-DM was found to be 40.55 ± 7.776 , 38.45 ± 9.659 and 36.85 ± 7.256 mg/dl respectively. Lastly, the serum TG level of healthy controls, Obese-NDM and Obese-DM was found to be 181.35 ± 83.42 , 197.65 ± 76.50 and 210.95 ± 83.84 mg/dl respectively.

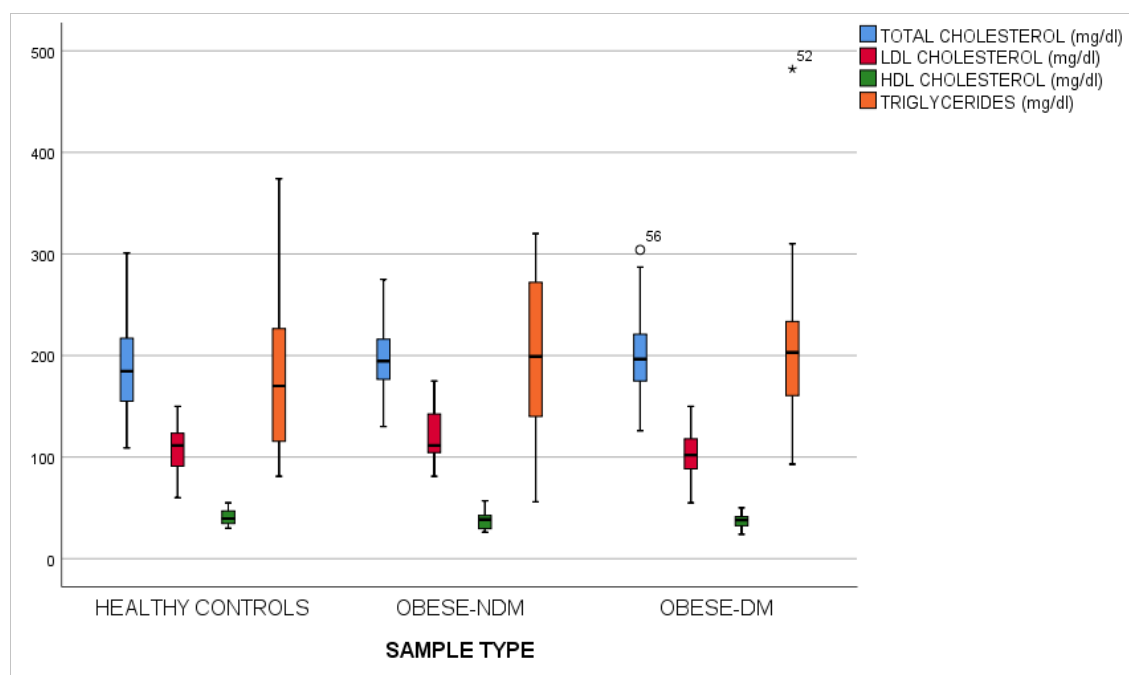


Figure 3: Box-plot analysis showing differences in fasting lipid profile tests namely serum total cholesterol, LDL cholesterol, HDL cholesterol and Tryglycerides of Obese diabetes mellitus, Obese-non-diabetes mellitus and Healthy Controls.

Group 1=Healthy Control, Group2= Obese-Non-Diabetes mellitus (Obese-NDM) Cases, Group 3 = Obese- Diabetes mellitus Cases (Obese-DM). Although the results showed marginal differences in the three sub-cohorts but it was not statistically significant due to low sample size.

Discussion

The present study was a hospital based case control study to understand the biochemical and molecular genetic basis of Obesity with special reference to Type 2 Diabetes. It included 40 obese subjects. These Obese subjects were divided into 2 sub-cohorts namely; Obese-Diabetes (n=20) and Obese-Non Diabetes (n=20). The Obese-Diabetes cases were newly diagnosed cases of T2DM with obesity. Few unmatched, unrelated healthy subjects (n=20) was also included in the study as healthy controls.

In the current study, the mean age of Obese-Non Diabetes was found to be 29.38 ± 4.47 while the mean age of Obese- Diabetes subjects was found to be 37.60 ± 4.808 which suggested that the prevalence of the disease in middle adulthood period of life. Different observations were noted by Ashraf R *et al.* [8].in their study in the year 2022, where mean age was 47.39 ± 12.61 years of obese-diabetic.

In our study, 55% (11 out of 20) diagnosed with Obese-DM were female while 45% (9 out of 20) were males with a female ratio of 1.2: 1. While recent studies [8] indicate that 42.5% (166 of 390) of the cases were males and 57.4% (224 of 390) were females with a male/female ratio of 0.7:1. Further, sedentary life style, frequent consumption of food and lack of exercise are the most important risk factors contributing to the development of Obese-diabetes. However, all Obese-DM subjects may not have a history of alcohol consumption and smoking.

In this study, insulin resistance was assessed by HOMA-IR (Homeostatic Model Assessment for Insulin Resistance). There are fallacies regarding normal cut off of HOMA-IR. HOMA-IR is expressed in population based percentile criteria. It differs depending on ethnicity, clinical methods of estimation and metabolic condition of the studies population. HOMA-IR value of more

than 2 is considered a significant insulin resistance. However a recent study revealed that a HOMA-IR cut off of 2.5 provided maximum sensitivity and specificity in diagnosing metabolic syndrome as per ATP III (Adult Treatment Panel III) and IDF (Internation Diabetes Federation) criteria [9]. In our study we found that HOMA-IR levels for were increasingly higher in obese-diabetic patients compared to healthy controls vis-a-vis obese-non-diabetic patients.

The HOMA-IR values were higher in obese-diabetes mellitus (4.495 ± 2.324) as compared to obese-non-diabetic patients (2.49 ± 0.621) and healthy controls (1.65 ± 0.513). It was found that in the HOMA-IR values were significant in obese-diabetic subjects compared to healthy controls ($p=0.078$). Thus it can be said that higher HOMA-IR values in obese-DM suggest significant insulin resistance as compared with obese-NDM and healthy controls. This clearly indicates that there is a consensus on HOMA-IR cut-off values for identifying Obese-DM cases from Healthy controls.

Abnormalities in lipid metabolism are very commonly observed in obese non-diabetic and obese diabetic patients who are obese. The lipid abnormalities in patients include elevated serum total cholesterol, triglyceride and lower HDL-C levels. LDL-C levels are frequently in the normal range but there is an increase in small dense LDL [10].

In our study, it was observed that the serum cholesterol levels in healthy controls, Obese-NDM and Obese-DM was found to be 194.05 ± 53.141 , 197.2 ± 35.952 and 201.00 ± 46.004 mg/dl respectively. The serum LDL-C levels in healthy controls, Obese-NDM and Obese-DM was found to be 108.55 ± 22.97 , 121.80 ± 26.49 and 103.20 ± 24.40 mg/dl. Further, the serum HDL-C level of healthy controls, Obese-

NDM and Obese-DM was found to be 40.55 ± 7.776 , 38.45 ± 9.659 and 36.85 ± 7.256 mg/dl respectively. Lastly, the serum TG level of healthy controls, Obese-NDM and Obese-DM was found to be 181.35 ± 83.42 , 197.65 ± 76.50 and 210.95 ± 83.84 mg/dl respectively. Although the results showed marginal differences in the three sub-cohorts but it was not statistically significant due to low sample size.

To conclude, various biochemical alterations depicts the picture of underlying metabolic derangements which has been linked with the pathogenesis of obesity associated T2DM. Further studies with larger sample size are required to confirm whether this association is actually prevalent in the population of Barpeta district of Assam.

Acknowledgment

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