Comparing capillary blood glucose measures with venous blood glucose evaluated by the diabetes unit of the AL-Sadder Hospital, Basra, Iraq.

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Key words: Diabetes Mellitus ; glucose meters and blood glucose.

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Abstract:

Diabetes Mellitus is a chronic disease associated with long-term complications, damage, dysfunction, and failure of different organs, including the eyes, kidneys, nerves, heart and blood vessels. Blood glucose monitoring by measuring glucose levels using test strips in home-monitoring or venous blood glucose measuring in laboratory can improve the monitoring of hyperglycemia in DM also can evaluat the patient complaince. Validation of accuracy and reliability of different glucometers is important to variation in measurements may be attributed to different factors, may be affected by the environment in which glucometers and strips are stored, user dependent factors (operational technique). The aim is to compare capillary blood glucose measures with venous blood glucose by different devices.

This prospective randomized study was conducted between January 2014 and May 2014 in Al-Sadder teaching hospital in Basra, Iraq, to compare the results of measurment blood glucose level of two glucose meters (AccuChek® active (Roche Diagnostics, Basel, Switzerland) and Optium Xceed® (MediSense UK, Abingdon, UK) with standard venous glucose measurment using spectrophotometry (hexokinase). One hundred non intensive care unit patients who had been admitted for a variety of medical and surgical problems had been included in the study. All the patients had previously been diagnosed with diabetes mellitus and under 60 years of age.The results revealed significant differences in glucose levels measured using optimal xeed glucose meter when we compared with Accu check glucose meter and those values measured using standerd venouse glucose mesurment. We conclude that The Accu check glucose meter was more accurate than xeed glucose meter, as compared with ordinary serum glucose measurement by spectrophotometer.

مقارنة قياسات السكر في الشعيرات الدموية مع مستويات السكر بالاوردة الدموية والمقيمة في وحدة السكري في مستشفى الصدر في البصرة –العراق

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الكلمات الدالة:مرض السكري؛قياس الكلوكوز وكلوكوز الدم, اجهزة السكر المنزلية وقياس السكر.

الخلاصة:

داء السكري هو مرض مزمن مرتبط بمضاعفات طويلة الامد وضرروعجز، وفشل الأجهزة المختلفة، بما في ذلك العينين والكليتين والأعصاب والقلب والأوعية الدموية. مراقبة مستوى السكر في الدم عن طريق قياس مستويات السكر باستخدام شرائط الاختبار في المنزل او قياس السكر بالدم الوريدي بالمختبر يمكن أن تحسن نسبة السكر في الدم في مراقبة مرضى السكري. التحقق من دقة وموثوقيةمختبلف اجهزة السكر مهم للتباين في القياسات يمكن أن يعزى إلى عوامل مختلفة، قد تتأثر بالبيئة التي يتم تخزين الاجهزة والشرائح و العوامل التي تعتمدعلى المستخدم (التقنية التشغيلية). الهدف هو مقارنة مستوى السكر في الشعيرات الدموية مع السكر في الدم الوريدي بمختلف الاجهزة.

اجريت هذه الدراسة العشوائية المحتملة بين يناير 2014 ومايو 2014 في مستشفى الصدر في البصرة، العراق ، لمقارنة نتائج قياس مستوى السكر في الدم في جهازين منزليين للسكر جهاز Optium Xceed® وجهاز AccuChek® active مع جهاز قياس السكر بالدم الوريدي. وكان مئة مريض من اللذين كان قد ادخلوانتيجة المشاكل الطبية والجراحية المختلفه أدرج في الدراسة جميع المرضى الذين شخصوا مسبقا بالسكري من النوع الاول والثاني وبعمر اقل من 60 عام . النتائج تكشف عن اختلافات كبيرة في مستويات السكرعند قياسها باستخدام جهاز Optium Xceed® عند مقارنته مع جهاز AccuChek® active وتلك القيم تقاس باستخدام قياس السكر العاد في مصل الدم بواسطة

مقياس الطيف الضوئي. نستنتج أن جهاز AccuChek® active اكثر دقة من جهاز optium Xceed® عند مقارنتها مع قياس السكر العادي بالدم بواسطة جهاز الطيف

Introduction

Diabetes Mellitus is a metabolic diseases characterized by hyperglycemia caused by decrease in insulin secretion, insulin action, or combination of both. Diabetes is associated with long-term complications, damage, dysfunction, and failure of different organs, including the eyes, kidneys, nerves, heart and blood vessels [(1)]. Blood glucose monitoring by measuring glucose levels using test strips in home-monitoring or venous blood glucose measuring in laboratory can improve glycaemia as a first in DM patients monitoring. Recently, many studies demonstrated that such monitoring was associated with decreased morbidity and mortality related to diabetes especially in type 2 diabetes patients [(2)]. Both type 1 and type 2 diabetes show a direct relationship between the degree of glucose control and the risk of systemic complications [(3)]. It is therefore recommended that all insulin-treated patients perform Self-monitoring of blood glucose to prevent and detect sever hypoglycemia associated with over treatment or some changes in lifestyle; it is also used in establishing the need for insulin therapy in patients with insulin dependent diabetes mellitus or gestational diabetes [(4)]. Till now, researches on self-monitoring has been focus upon glycosylated haemoglobin (as measured by HbA1c) as the sole outcome measure for previous monitoring [(5,6)]. Self-monitoring is often recommended for people newly diagnosed diabetes mellitus [(7)]. Glucose meters and glucose sensors play crucial role in the modern management of diabetes. Glucose meters are important for clinicians, manufacturers, and most importantly, for patients who wish to achieve optimal control of blood glucose for improved clinical outcomes [(8)]. Management of both hypoglycemic and hyperglycemic disorders required rapid and precise monitoring with aim of adjusting glucose to a near-normal range [(9)].The magnitude of the error is dependent on monitoring system and specific combination of mismatched codes[(10)]. Such errors are critically important because they have the potential to cause errors in the correction scale insulin dose administered or in dose calculation of anti-diabetic drug used [(11)]The objective of the present study was to compare the capillary blood glucose values obtained by two different glucose meters and to determine the accuracy of those measurements relative to serum glucose values of inpatients at AL-Sadder Hospital in Basra, Iraq.

Patients and methods

The present study was a randomized, prospective, open, unicenter study was conducted in Al-sadder teaching hospital in Basra, Iraq. 100 non intensive care unit patients who had been admitted for a variety of medical and surgical problems had been included in the study. All the patients had previously been diagnosed with type one or two diabetes mellitus and under 60 years of age, all patients were hemodynamically stable during samples collection. Unstable glycemic control, lack of legal capacity, pregnancy, and patients taking other medications could interfere with results were excluded from the study. Venous blood glucose values were obtained through an enzymatic process that uses the enzymes hexokinase and glucose-6-phosphate dehydrogenase. Meanwhile after contact with capillary blood, the test strip of the AccuChek® (Roche Diagnostics, Basel, Switzerland) filters out the red blood

cells and allows plasma to be in contact with the reagents. Glucose is oxidized by the enzyme glucose oxidase in the presence of atmospheric oxygen, thus producing hydrogen peroxide (H_2O_2). This compound reacts with a specific dye and produces a chromophore, a light-absorbing dye. Subsequently, a light-emitting diode emits a specific light on the dye, and the reflected light is absorbed by a sensor that converts it into electronic signals. The intensity of the color generated at the end of the reaction is proportional to the glucose concentration in the sample. Based on medical records, data were collected from all patients who were initially diagnosed with diabetes between January 2014 and May 2014. Glucose meters included in the present study, AccuChek® active (Roche Diagnostics, Basel, Switzerland) and Optium Xceed® (MediSense UK, Abingdon, UK) glucose meters. The principle of these meters based on two essential parts: an enzymatic reaction and a detector. The enzyme portion of the glucose meter is generally packaged in a dehydrated state in a disposable strip or reaction cuvette. "Glucose in the patient's blood sample rehydrates and reacts with the enzymes to produce a product that can be detected. Some meters generate hydrogen peroxide or an inter-mediary that can react with a dye, resulting in a color change proportional to the concentration of glucose in solution". Other meters incorporate the enzymes into a biosensor that generates an electron that is detected by the meter. There are three principle enzymatic reactions utilized by current glucose meters: glucose oxidase, glucose dehydrogenase, and hexokinase. Each enzyme has characteristic advantages and limitations. These two meters were chosen because they are accepted by the regulatory agencies and was available at all study sites.

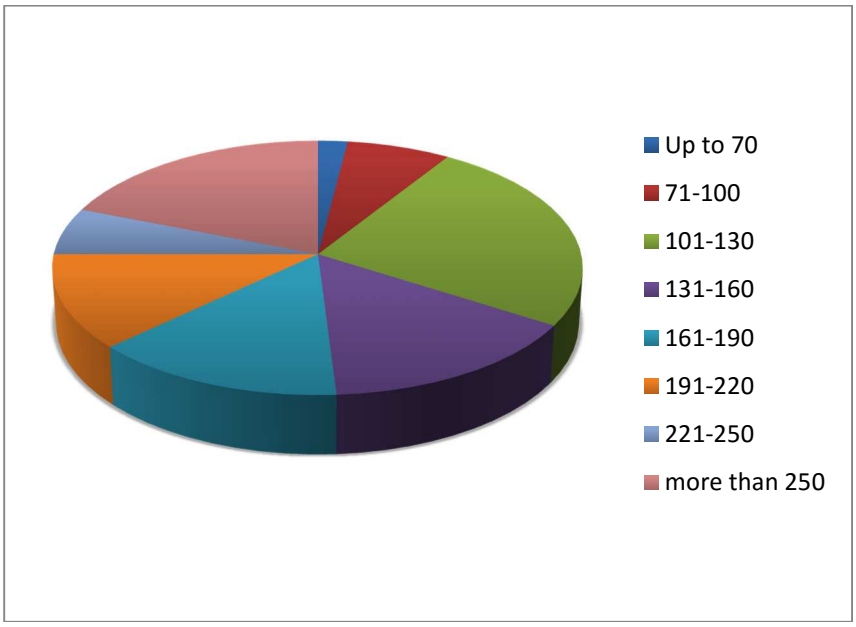
The capillary and serum blood glucose samples were collected simultaneously from the fingertips ipsilateral to the arm from which the venous blood was collected, always 2 hours after the patients' lunch, and immediately taken to the laboratory in order to prevent glycolysis.

Statistics

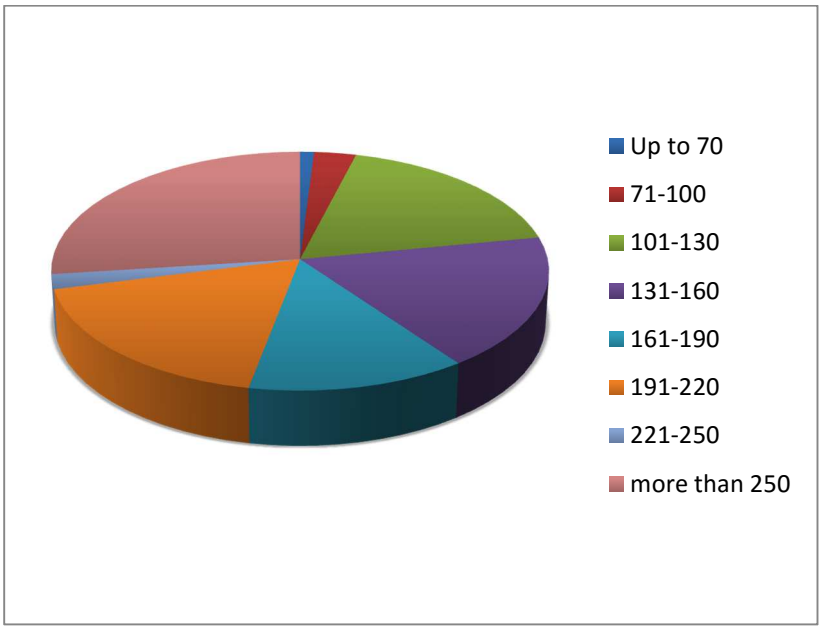
Values were expressed as mean ± S.D; the values were statistically evaluated using unpaired Student's t-test and correlation analysis Values with $P < 0.05$ were considered significantly different. Analysis was performed using GraphPad Prism software and Microsoft excel analysis

Results

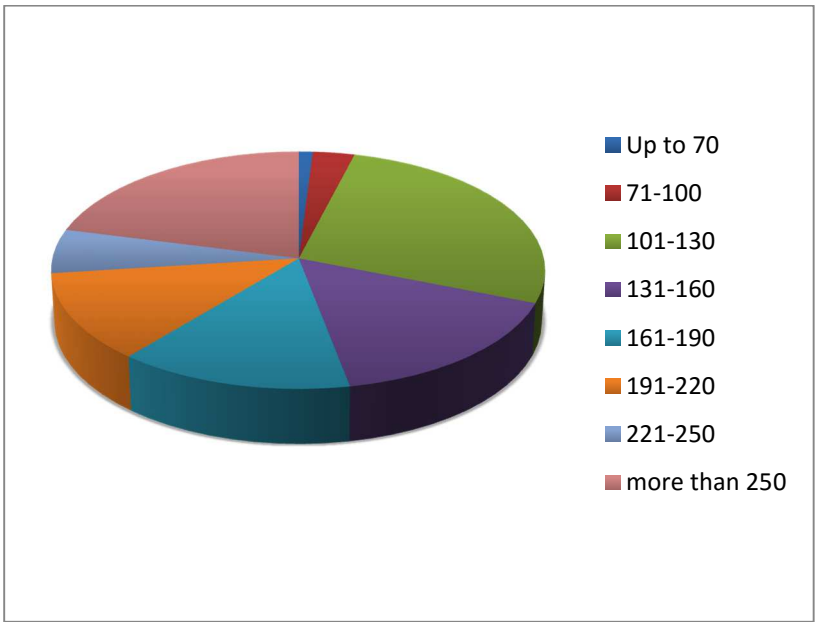
A total of 100 patients with type 1 and 2 diabetes mellitus were selected and participated in the present study. Figures 1, 2 and 3 depict distribution analysis of blood glucose ranges measured by venous glucose measure, Optium xeed glucose meter and Accu check glucose meter, respectively. Highest blood glucose ranges observed in values more than 100mg/dl and lowest ranges observed less than 100 mg/dl.



Figure(1)Distribution in blood glucose ranges of the measurements obtained by venous glucose measure.

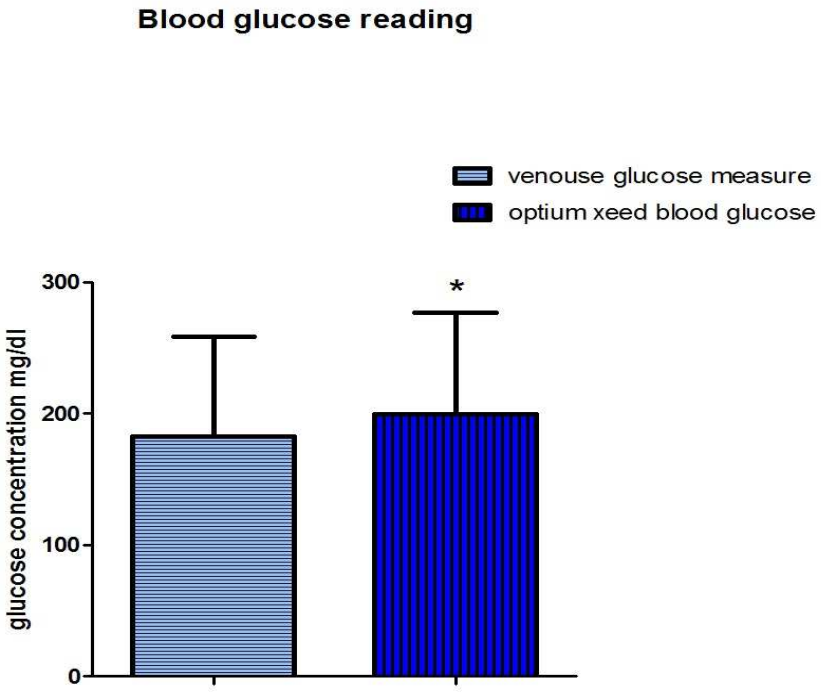


Figure(2)Distribution in blood glucose ranges of the measurements obtained on Optium xeed glucose meter



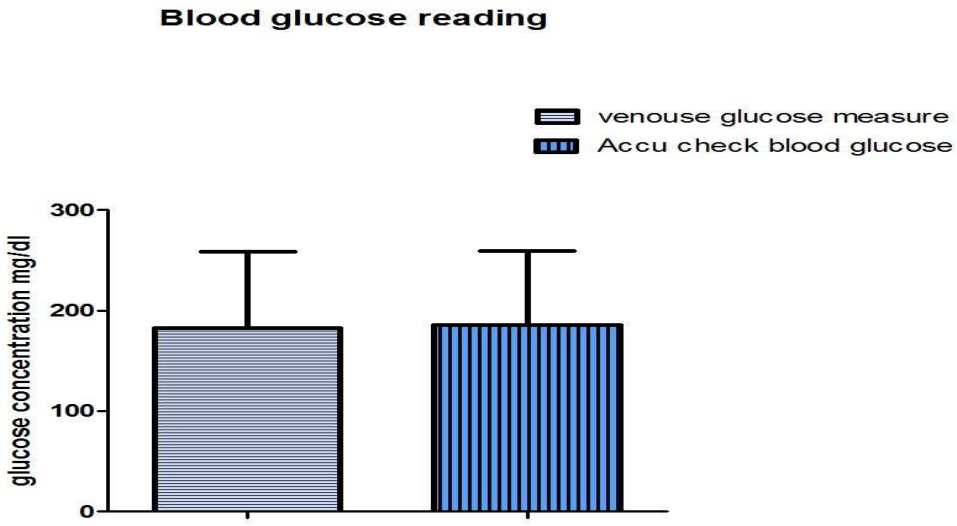
Figure(3) Distribution in blood glucose ranges of the measurements obtained on Accu check glucose meter

Figure 4 shows that blood glucose values for diabetic patients measured by optium xeed significantly higher than that observed by standard venous glucose measured for same patients.



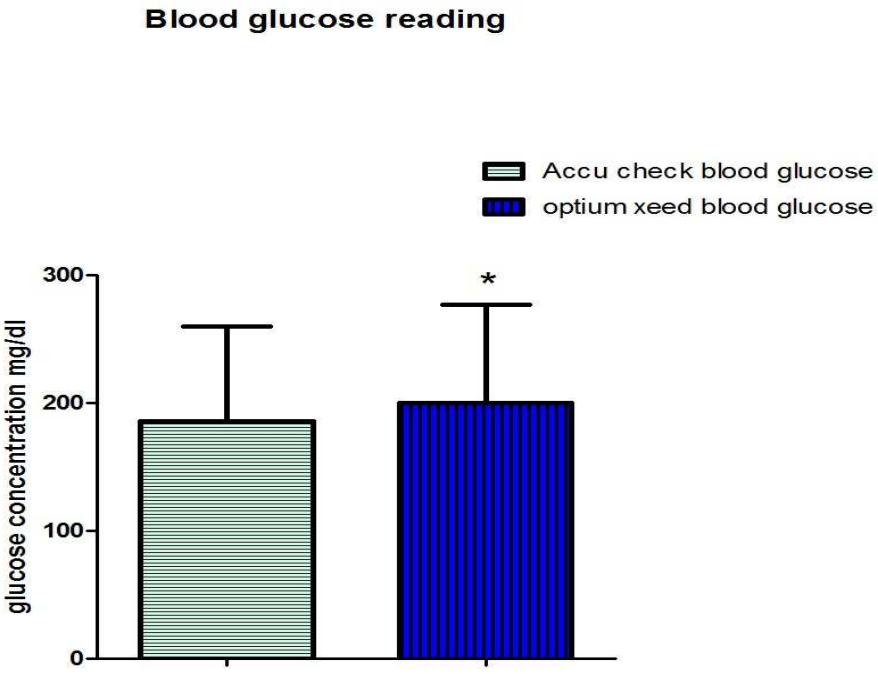
Figure(4)Blood glucose concentration measured by standard venous glucose measure and using Optium xeed glucose measure. * significant differences (P<0.05)

Figure 5 compared blood glucose measured by Accu check and standard venous glucose measure where no significant difference was observed between two methods.



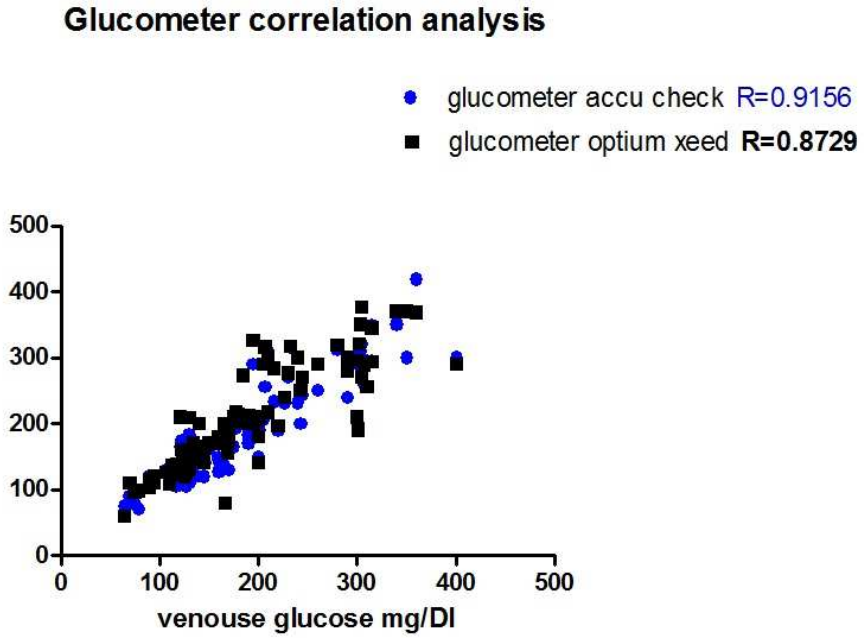
Figure(5)Blood glucose concentration measured by standard venous glucose measure and using Accu check glucose measure. No significant differences observed.

The values of blood glucose measured using Optium xeed glucose meter significantly higher than that measured by Accu check glucose meter as shown in figure 6.



Figure(6)Blood glucose concentration measured by Accu check and Optium xeed glucose meters. * significant differences (P<0.05)

In figure 7 correlation analysis between venous glucose and those measured using the two tested glucose meter were done, significant positive correlations were observed



Figure(7) Correlation analysis between venous glucose level versus blood glucose measured using accu check and optium xeed glucose meters. Significant positive correlation was observed.

Discussion

The present study was conducted to test accuracy and reliability of different glucometers in Basra, Iraq. The results reveals significant differences in glucose levels measured using optimal xeed glucose meter when we compared with Accu check glucose meter and those values measured using ordinary serum glucose measurement by spectrophotometer(hexokinase). Such variation in measurements may be attributed to different factors, may be affected by the environment in which glucometers and strips are stored, user dependent factors (operational technique)[12]**.** Hand washing with warm water and dry hands thoroughly is important, In addition volume of blood with drawn is critical factor [13]**,** many drugs taken by a patient may interfere with glucose meter reading and patients taking such drugs could gave false results [14]. Furthermore sampling methods, devices used for measurement, or both contribute to the observed inaccuracy of instruments[15] . Kinchiku et al demonstrated that ambient temperature can significantly affect blood glucose monitoring and this should be consider as important factor determining glucose measure add to that Meters should be protected during transport against heat and humidity of summer or cold of winter [16]. In general many meters have blocking patient results or displaying an error code when the ambient conditions of temperature and humidity are outside manufacturer ranges by having internal temperature checks that prevent use of the meter outside of acceptable tolerance by Ccalibration of glucometers are essential, this can be performed manually by the user or automatically by the blood glucose monitoring system, such calibrations error by the user[17] . Many studies were done to evaluate the accuracy of different glucometers in different countries. Hoedemaekers et al conclude that glucose results

from three testing devices were inaccurate in both intensive care unit and non-intensive care unit patients.

In other study done by Freckman et al, show that 7 glucometers out of 34 devices are in accurate and they recommend regular and standardized evaluation of glucometers and test strips should be performed in order to ensure adherence to quality and accuracy standards and to reduce the risk of false therapeutic decisions [(18)]. On the other hand it has been shown that measurement of glucose level using different glucometers was to be the most accurate and reliable in comparison with glucose oxidase reference method were measurement are comparable[(19)]**.** General speaking, environmental conditions should be aware by both clinicians and patients because they may affect the of test strip performance.

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