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Comparative Study for The Precision and Possible Interference of Some Drugs with Glucometer Measurements Commonly Used In Iraq

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ABSTRACT:

Glucose control is very imperative in diabetic patients, and the prevalence of diabetes has been increasing in various countries over the past few years. Insulin and oral hypoglycaemic drug dosing are based on measurements performed with glucose meters. Therefore, meter precision can have a major impact on insulin dosing accuracy. Inaccurate blood glucose other hypertensive and anti-inflammatory drugs. The purpose of the current study done by some students in the Pharmacy Department at Al-Rasheed University College in Baghdad, Iraq, from October through December 2022 is to compare the accuracy of three glucose meters (Accu-Check, VivaChek, and Prodigy) widely distributed and marketed as portable glucometers used by Iraqi diabetic patients in two separate studies, one for glucometer precision and the other as a comparative study for possible blood glucose measurement interferences with Acetaminophen and Ascorbic Acid. The devices used had different mechanism of the test strip. The study results indicated significant blood glucose–acetaminophen interference differences. However, there was no marked interference with ascorbic acid, and relatively consistent readings for the precision test over three days among the three tested glucometers

KEYWORDS: Glucometers , Vitamin C, Acetaminophene, Accu-Check, Precision.

INTRODUCTION:

Diabetes mellitus (DM) is a metabolic disease characterised mainly by hyperglycaemia and brought on by partial or complete insulin deficiency , the goal of therapy is to personalize treatment with medication based on individual factors such as age, duration of the disease, presence or absence of diabetes complications, underlying pathophysiology, and risk/bene.t of each medication and their combination [1,2] . According to (Yang et al. 2010) previous study , the age-standardised prevalence of diabetes and prediabetes is about 9.7% and 15.5% for 20 years of age or older respectively, accounting for 92.4 million adults with diabetes and 148.2 million adults with prediabetes. [(3)] Even though they are short term signs and long-term complications of diabetes arise from chronic hyperglycaemia and can cause microvascular issues in the kidneys, peripheral nerves, or retina. And macrovascular consequences of diabetes as myocardial infarction, stroke, and peripheral artery disease happen more frequently, yet these symptoms don't adequately describe the condition because they are usually present in the prediabetic condition [1,4] . Clinicians detect glucose in a variety of body fluids, including blood. Modern enzymatic approaches have taken over the role of earlier reduction and condensation methods for the measurement of blood glucose and are available for diabetic patients in markets all over the world with different companies[3] . The threshold used to classify something as normal or abnormal, as well as the advised technique for monitoring plasma glucose, has changed over the course of the last few decades by which complications from diabetes can be avoided by regularly monitoring and keeping

blood glucose levels within the normal range [5] . The accuracy profile of each glucometer varies, with some meters being less accurate around low glucose levels, which is undoubtedly the most worrisome range for critically ill patients who frequently cannot communicate hypoglycaemia symptoms and glucose control is very significant in diabetic patients; therefore, conservation of blood glucose between 80 and 110 mg/dl not only reduce the morbidity and mortality associated with diabetes, but also contribute to the ever-growing costs related to diabetes. Adoption of appropriate diet and exercise behaviors and adherence to medication regimens will result in tighter glycemic control. [6,7] .

The management of diabetes is a challenge, and it has paid much attention to monitoring blood glucose in diabetic patients to achieve tight glycemic control and minimise complications can be helpful in treatment of diabetes[8]. Management of diet with less sugar consumption, involving in physical exercise ,weight loss training should be recommended [9]. Since insulin and oral hypoglycaemic drug dosing are frequently based on measurements performed with glucometers, Thus, the precision of the glucometer could have a significant impact on the dosing accuracy [10,11]. Some previous studies reported that many commonly used drugs and chemicals affect the accuracy of glucometers, such as ascorbic acid, acetaminophen, and dopamine[12]. To our knowledge, there are no clinical studies or research for estimation of glucometer precision or their possible interference in Iraq or nearby countries; this study thus this study aims to measure the accuracy and precision of three different commercially available glucometers from different companies common locally in Iraq with the estimation of the possible interference of acetaminophen and ascorbic acid in low and normal plasma glucose pools and to measure their accuracy for three days in plasma pools spiked with glucose alone, as well as in normal and low glucose pools.

METHODOLOGY :

This comparative study was conducted in two parts , First to determine the accuracy and Second to estimate the possible measurments interference of acetaminophen (paracetamol) and ascorbic acid (vitamin C) with serum glucose levels measured by the most widely used glucometers in Baghdad, Iraq. 10 ml of blood samples were collected from thirty healthy male and female students of age range (18–25) years from the pharmacy department at Al-Rasheed University College took part in this study as healthy volunteers . After the interview, each volunteer signed approved consent form of the ethical committee of Al-Rasheed University College, Iraq . Exclusion criteria include diabetics, hypertensives, pregnant and smokers. Any participant taking drug therapy for the disease should discontinue it for three days before enrolling in the study with an overnight fasting state. Two 8-ml heparin lithium tubes were used to collect blood sample drawn from each volunteer and then centrifuged at 3000 rpm for 5 minutes to get plasma sample then separated plasma for all volunteers were mixed in one pool and stored refrigerated at (-20°C) , marked as “Normal glucose concentration pool”. The other plain tubes contained separated plasma samples that were left overnight at room temperature to allow complete glucose degradation and hemolysis, then these plasma samples were centrifuged to separate plasma and give a “low glucose concentration pool”. Collected plasma samples from both pools were measured five times using three most widely diabetic patients used glucometers (Accu-Check®, Viva-Chek®, and Prodigy®) . Baseline measurements were estimated without adding any interferening substances (acetaminophen, vitamin C, or dextrose) (Fig 1.)

Figure-1. Methodolgy Diagram

Stock solutions of spiking dextrose and interfering substances preparation

Stock solutions of dextrose used for precision study and serial dilutions were obtained as (20, 40, 60, 120, 400 mg/dL of dextrode/water) .interfering substances (acetaminophen and ascorbic acid) were prepared in different concentration (Acetaminophen: 5 mg, 20 mg, 32 mg, 80 mg, 100 mg) while Ascorbic acid: 5 mg, 10 mg, 25 mg, 50 mg, 200 mg) prepared for interference study part during thawaing the stored frozen plasma samples to reach room temperature. For baseline measurements, ten 0.5 ml portions of plasma used for measuring the possible glucose reading interference of each interfering substance, using five Eppendorf tubes per pool. Then each Eppendorf tube tested five times for each glucometer chosen for presicion testing of the devise accuracy involved plasma portions spiked with dextrose in diferent concentration and tested once a day for three days in a row. During two days , on days 2 and 3, dextrose-spiked pool were tested for precision, with baseline readings also continuing. For interrefnce study, different concentrations of acetaminophen, ascorbic acid, used for normal and low levels glucose pool measured before and after addition using on each of the three glucometeres compared as shown in Schematic diagram (Figure 1)

Statistical Analysis

Statistical analyses made using Microsoft Excel 2016 to analyse the data collected from the study results and Transfer the data to Excel sheets to compute the mean, Standered deviation , and confidence coefficient , as well as the coefficient of variation (COV%) . A p-value less than 0.05 indicates that statistically significant .

RESULTS AND DISCUSSION:

Table 1. showed the baseline of Vitamin C in the normal pool is 123.8 mg/dl for Accu-Check, 107.2 mg/dl for Viva-Check, and 134.8 mg/dl for Prodigy-Auto Code Check. The baseline, in the low pool, is 13.4 mg/dl for Accu-check®, 0 mg/dl for Viva-check®, and 4.87 for Prodigy-auto code check®. The interference effect of vitamin C, acetaminophen, and dextrose was tested at two levels of blood glucose, low and normal concentrations . Five vitamin C concentration (5, 10, 25, 50, and 200

mg/dl) and Acetaminophen (concentrations of 5, 20, 32, 80, and 100 mg/dl). Were used as interfering substances.

Glucometers Precision Testing

Precision testing mesurments done for plasma samples spiked with dextrose in different concentrations , each aliquot was tested five times per device, compared to base line measurments. Table (1) , Figure (1) showed the coefficient of variation (COV%) versus dextrose concentration bar charts for Precision Experiment for three days.The low and normal pool was considered with concentration of dextrose (2, 4, 6, 12 mg/dL) to test the precision of the three devices. The coefficient of variation (COV%) is a statistical measure that expresses the standard deviation of a data set as a percentage of the mean.

COV% = (standard deviation / mean) x 100%.

Table 1 . The baseline plasma glucose level measurements for each glucometers

KEY	Stock 1	Stock 2	Stock 3	Stock 4
1% Dextrose / water stock solution	120mg/dl	60mg/dl	40mg/dl	20mg/dl

Accu-Chek normal plasma glucose pool mg/dl							Accu-Chek low plasma glucose			
	Stock1	Stock2	Stock3	Stock4	Baseline			Stock1	Stock2	Stock3
Day1	237.4	190.2	150.2	141.8	119.4		Day1	168.2	88.8	60
Day2	205.4	175	131.4	135.2	114.6		Day2	183.8	101	65.2
Day3	189.4	145.6	110.4	127.8	118.2		Day3	175.4	90.8	54.4
Viva-Chek normal plasma glucose pool mg/dl							Viva-Chek low plasma glucose			
	Stock1	Stock2	Stock3	Stock4	Baseline			Stock1	Stock2	Stock3
Day1	268	187.2	144.8	129.6	104.8		Day1	179.4	82.4	49.4
Day2	231.2	179	130.2	107.2	105.2		Day2	195.4	86.2	45
Day3	182.2	136.4	92.8	108.4	105.8		Day3	182.2	74.2	31
Prodigy-Autocode normal plasma glucose pool mg/dl							Prodigy-Autocode low normal plasma g			
	Stock1	Stock2	Stock3	Stock4	Baseline			Stock1	Stock2	Stock3
Day1	255.4	190	155.8	139	136.8		Day1	191	103.8	69.4
Day2	269	203.6	146	150.6	133.4		Day2	201.6	114	75.8
Day3	203.2	157.6	120.4	129.8	130		Day3	203.6	105.4	60.4

It is a useful tool for comparing the variability of two or more data sets with different units of measurement or different means. The COV% allows us to determine which data set has greater variability relative to its mean.

The produgy® and vivacheck® displayed “Lo” sign in low pool when concentration was 20 mg/dL.

For Accu-Check® device , The CV% was > 5% at concentrations 20 mg/dL of dextrose at low pool, , VivaChek® device, CV% was > 5% at concentrations 40, 120 mg/dL (day1), 40, 60 mg/dL (day2), 20, 60 mg/dL (day3) at low pool. Prodigy AutoCode® device, the CV% was > 5% at concentrations 40, 60, 120 (day1), 20 (day2) 40, 120 (day3) at low pool. Prodigy AutoCode® device at normal pool, the CV% was larger than 5% at concentrations 40, 60 (day1), 20, 40, 120 (day2), For these concentrations, the coefficient of variation (COV%) was higher than for others, indicating a higher degree of variability and potentially lower precision in the readings obtained from these devices. A higher COV% could potentially affect the accuracy and reliability of glucose measurements (Figure 2) .

Figure 2. The coefficient of vatiation (COV%) versus dextrose concentration bar charts for precision experiment for each glucometer commonly used in Iraq.

Figure 3. Effect of vitamin Con glucose readings in the normal and low normal pool, for three devices.
(A) This graph shows the readings of glucose compared to concentrations of vitamin C. The concentrations of vitamin C are (5, 10, 25, 50, and 200 mg/dL) in the normal pool. For the Accu-Chek device with a P-value of 0.33, vitamin C appears to have a significant effect on this readings, leading to low glucose readings when increasing the concentration of vitamin C. This effect is more pronounced in the normal glucose range than in the low glucose range
(B) The Accu-Chek, in low glucose with a P-value of 0.353, showed that there was an increase in glucose readings with an increase in concentrations of vitamin C. The low glucose readings for the other devices were equal to zero.
(C) The Prodigy Auto code device with a P-value of 0.08 also showed an uneven change in its readings, with an increase in readings after adding vitamin C in some concentrations and a decrease in readings in others in the normal glucose range. In the low glucose range, we observed a two-degree increment.
(D) The Viva-Chek device with a P-value of 0.5 showed an uneven change in its readings in the normal glucose range, with a decrease in readings at lower vitamin C concentrations (5, 10 mg/dl) but an increase in readings at higher vitamin C concentrations (25, 50, 200 mg/dl). However, the increase is only slight to moderate, suggesting that the interference from vitamin C is insignificant. In the low glucose range, non significant changes observed in the readings after adding vitamin C.

Interference of Vitamin C on glucometers measurments

Millions of people with diabetes use portable blood glucose meters to measure blood glucose values every day as an aid in diabetes self-management . Patients use these devices in a variety of settings, including homes and workplaces [13]. Interference study results in (figure 3) showed the extent of mean blood glucose measurments changes after interfering with Vitamin C, in the normal plasma glucose pool were 112.667mg/dl for Accu-check®, 109.467mg/dl for Viva-check® and 135.6 mg/dl for prodigy-auto code check ® ,compared to low plasma glucose pool measurments (16.8 , 0 , and 4.87) mg/dl respectively for the same devices used in this study . The Accu-Chek® device readings are "confident" because they are consistent with our expectation that the true population mean falls within the calculated interval with a high degree of probability (in this case, 95%). However, for the low glucose conditions of the Viva Chek® and Prodigy AutoCode® devices, the confidence intervals are unreported because the values are zero. This means that there is no variance in the data and no need to calculate a confidence interval. It's critical to note that the degree of overlap in the confidence intervals can indicate the degree of similarity or difference between the readings obtained from different devices. However, it's also imperative to consider other factors that can affect the accuracy and reliability of the readings. These factors include experimental conditions and the quality of the devices themselves.

Results of this study come in agreement with some previous studies showed that ascorbic acid is a common substance interfering with glucose meters with a slight variations in glucometer accuracy [14,15]. Based on the study results there is a clear overlap between all concentrations of vitamin C for the Accu-Chek ®device in both normal and low glucose conditions, as well as for the VivaChek® device in normal glucose conditions and the Prodigy AutoCode® device in normal glucose conditions the possible effects my related to vitamin C. According to (Cho J. et al 2016) , the possible explanation for this effect related to vitamin C as strong antioxidant that inactivates free radicals and can be oxidized at the surface of electrochemical strips producing electrons and increasing the current , leading to reading variaiation [16,17] .

Figure 4. Effect of Acetaminophene on glucose reading in the normal and low normal pool, for three devices.

Interference of Acetaminophen on glucometers measurments

Acetaminophen is a popular non-opioid antipyretic and analgesic drug for pain and fever treatment, but it has limited antiflammatory effect [18] . The mean glucose readings after interfering with acetaminophen in the normal and low pools were 123.993 and 14.2 mg/dl for Accu-check®, 112.867 and 0 mg/dl for Viva-check®, and 243.467 and 162.267 mg/dl for Prodigy-auto code check® respectively. (Figure 4) Acetaminophen (sample concentrations of 5, 20, 32, 80, and 100 mg/dL) interferes with plasma in the normal and low pools.

The Accu-Check® device in normal and low pools (A) and (B) shows a very slight decrease in glucose readings in some concentrations and no change in others after adding the acetaminophen interference, providing evidence that the device may be slightly affected by the interference, but to a tiny extent. The same. P-values =0.546 and 0.242 show that the correlation is not significant at the 5% level. For (Figure 4 C&D) based on the experimental results, the Prodigy AutoCode® device with a P-value of 0.001 showed a significant increase in glucose readings. When testing both normal and low glucose samples with increasing concentrations of acetaminophen, there was a significant increase in the readings compared to baseline. Clearly showed the highest reading at a concentration of 100.

This suggests that acetaminophen can interfere with the accuracy of glucose measurements using the Prodigy AutoCode® device. Overall, this device appears to be the most sensitive to the interference of acetaminophen compared to the other devices tested. P-value 0.001 in the normal and low pools. A p-value less than 0.05 is significant, showing that the correlation coefficient is unlikely to be due to chance alone. A p-value less than 0.05 shows that the correlation is significant at the 5% level, meaning that it is unlikely to have occurred by chance. (Figure 4E) The Viva Chek® device with a P-value of 0.555 shows that the glucose reading was affected by acetaminophen concentration 5, which impacts the device's accuracy and reliability.

From the tables in the index of the 95% confidence interval for three devices, we notice that there is a clear overlap between all concentrations of acetaminophen on the Accu-Chek® device in both normal and low glucose, as well as for the VivaChek® device in normal glucose. For the Prodigy AutoCode check® for low glucose, there is no overlap in any of the ranges. This suggests a significant difference in the measurements taken by this device compared to other devices. For the normal glucose condition. The failure of the glucometers may arise from one of three aspects: failure in their precision, failure in their accuracy, or failure in their interference with medicinal drugs. [13.] It has become clear that these different use settings comprise distinct intended use populations with distinct characteristics and different device design specifications. Manufacturers should consider this when designing their devices .

This study results showed that the accuracy of the studied glucometers can be affected by interfering substances such as

vitamin C, and it's imperative to be aware of this when interpreting glucose readings and making clinical decisions based on these . Furthermore, (Brooke et al.2021) demonstrated that out of three hospital-grade glucometers, two of which showed a faulty increase in their readings of glucose when the vitamin C concentration was elevated, the third meter had a certain threshold above which it would show an error message and not provide a reading. [19,20] Morover , (Kirrane et al. 2009 and Ulfa Kholili et al 2023) highlighted the possible precision errors ,occur when the glucometer reads other carbohydrates as glucose polymers (maltodextrin) as if they were glucose, causing falsely elevated results ,which lead to further unnecessary administration of insulin, which could lead to severe hypoglycaemia, or the patient may already be hypoglycaemic [21,22] . A previous study conducted in Cameroon between 2013 and 2015 by (Klonoff et al. 2018) revealed that the accuracy of 18 devices (90% of commercially available devices) only met all the standards in three tests, five met them only in two, three met them only in one test, and four did not meet the standards in any study and showed that none of the devices tested had satisfied all the international recommendations that account for technical accuracy. Therefore, caution should be exercised when interpreting the results, and additional testing or investigation may be necessary to confirm the findings [23].

CONCLUSION:

This study showed that, based on the obtained results, it seems that a branded glucometer (Prodigy) gave elevated glucose level readings for acetaminophen interference than others (Accu-Check Active and Viva Chek). While it gave similar results with Vitamin C (ascorbic acid), however, there are non-significant differences in precision results among the three tested glucometers for dextrose spikes. Finally, the study concluded that glucometer users should be aware of possible reading errors during their drug therapy with other drugs for diseases other than diabetes.

RECOMMENDATIONS FOR FUTURE WORK :

The research team was limited by time and chemicals availability so a longer study period with other brands of glucometers and interfering chemicals will be more informative and complete what began through this study in the future.

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DECLERATION OF INTREST:

The authors declare no conflict of interest conserning this study.

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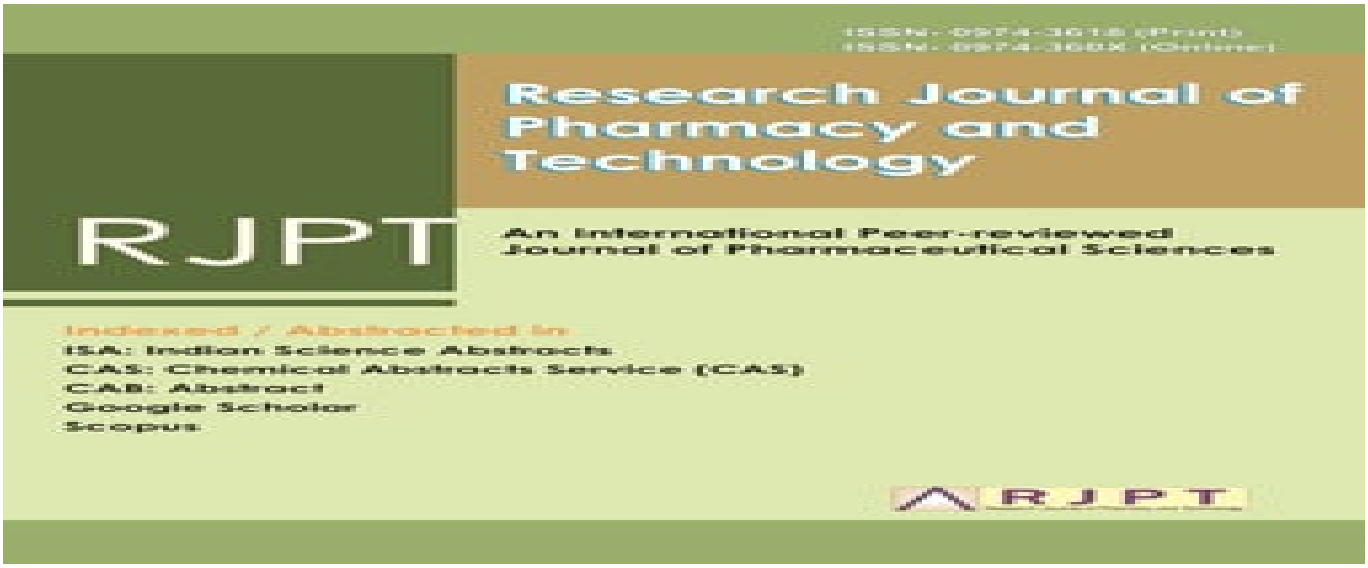

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