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Association between Plasma and Urine Glucose Measured using a Dry Chemistry Test Strip

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ABSTRACT

Testing the presence of sugar in urine will serve as an additional diagnostic tool to verify and correlate with the glucose level in plasma. The earliest test was done by using benedict's reagent and the reports were given ranging from nil to several positives depending upon colour changes. Dry Chemistry is now emerging as the latest technology for detecting sugar in urine, both qualitative and quantitative and some companies have developed instruments to read the intensity of colour obtained using reflectance principle and to report the urine sugar results quantitatively. Several commercial brand of test strips are available for urine sugar testing and many studies have been done in evaluating their merits and demeirts. This research paper is an attempt to find out the correlation between plasma and urine glucose both estimated quantitatively. Good correlation was found between plasma and urine glucose (P<0.00001). While dialab reagents and DIRUI CS 1300B analyser were used to measure plasma glucose, DIRURI H 100 reflectance analyser and multistix marketed by the same company was used to measure urine glucose. This research work suggests that every lab using quantitative urine glucose measurement based on dry chemistry test strips should evaluate its performance.

Introduction

Glucosuria results from the glomerular filtration of more glucose than the renal tubule can reabsorb. It occurs in all normal individuals in amounts up to 5 mg/dL. The glucose that is filtered through the glomeruli is reabsorbed by the proximal renal tubule and hence glycosuria represents an abnormal plasma glucose in the absence of renal glycosuria. The amount of glucose not reabsorbed by the kidneys is usually less than 0.1%. Adults excrete about 65 mg of glucose per day and standard techniques do not detect this level.

As early as the 1880's, some practitioners and pharmacists tried to replace the complicated wet-chemistry procedures and apparatus by "dry chemistry." A methodological breakthrough was created by the spot test chemistry inaugurated by the Austrian, Fritz Feigl in 1920. In 1956, the triumphal progress of the "stick tests" began with the "Clinistix" (Ames Company, today Bayer Diagnostic).(1) Glucose oxidase paper strips for semiquantitative determination of glucose in urine are commercially available but details of their preparation are not published. R-strips were evaluated against random urine added with various amounts of glucose in comparison with a commercial strip (T-strip), Benedict's test, and a commercial tablet (C-tablet), routinely used in the laboratories. The developed strips were found to be as specific as T-strip and more sensitive than other tests.(2)

Four commercial products for urine glucose determination were evaluated and compared with a quantitative hexokinase procedure. They are Chemstrip uG , Tes-Tape, Diastix (Ames), and Clinitest (Ames). Of the four products, Chemstrip uG had the lowest within-technologist and technologist-to-technologist random analytical errors. In method comparison on patients' samples, Chemstrip uG was significantly stronger in its association with the quantitative hexokinase method than was Diastix, Clinitest, or Tes-Tape. The urine glucose concentration is commonly used to monitor indirectly the degree of hyperglycemia in critically ill patients and to adjust insulin dosage. Most commercially available urine glucose reagent test strips measure the urine glucose concentration from 0% to 2%. When the urine glucose is at the 2% level, the blood glucose concentration may vary over a wide range. Test strips measuring from 0% to 5% are superior to conventional 0% to 2% test strips because the 3% and 5% urine glucose readings allow for a high level of specificity in detecting severe hyperglycemia (greater than 250 mg/dL) and urine glucose testing is insensitive and nonspecific in detecting hyperglycemia when urine glucose values are 2% or less.(3)

When semiquantitative urinary determinations were compared to plasma glucose stratified into 0 to 149, 150 to 199, and greater than 200 mg/dL, 75% of the urine samples associated with plasma levels from 150 to 199 mg/dL were negative by Diastix, and 16.5% of samples negative by Diastix were in the 200+ mg/dL plasma range. Only 9% of samples from 0 to 149 mg/dL showed any positive Diastix readings, because of the low sensitivity of semiquantitative methods. Except for detection of marked hyperglycemia, spot urine glucose determinations are inadequate as the sole means of clinical assessment for management of diabetic patients. Home glucose monitoring may be a better alternative for follow-up of these patients.(4) Diagnostic reagent strips are commonly used in clinical analysis of urine and blood, in particular for monitoring glucose concentration. Results are obtained instrumentally or visually as thresholds and

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quantitative outputs. Dry reagents are applied in the construction of strips in a variety of ways.[5] For most patients with type 2 diabetes mellitus (T2DM) not using insulin, use of glucometer for frequent self-monitoring (7 times a week) is unlikely to represent efficient use of finite health care resources, although periodic testing (at 1 or 2 times per week) may be cost-effective.[6]

Urine glucose testing using dry chemistry test strips have been suggested by some as nonessential in the management of DM since the technique and equipment for self-monitoring of blood glucose has become available. Urine glucose testing may provide a reliable backup for suspect whole blood glucose values and may prevent catastrophic events requiring expensive hospitalization. A study delineates several potential procedural problems that exist in the technique of whole blood glucose monitoring and provides recommendations to overcome these deficiencies.[7] Test strip use increased by almost 250% from 1997 to 2008, with 52.6% (n = 263,513) of included patients receiving a prescription during 2008. Almost half of these patients were at low risk for drug-induced hypoglycemia. In 2008, over 117 million test strips were dispensed in Ontario; however, more focused policy scenarios could have reduced this number between 9.5 million and 74.5 million test strips.[8]

CSF was tested using Combur-10 (Boehringer Mannheim) urinary reagent strip as an index test, and CSF microscopy and biochemistry as reference standards. Combur-10 is a urinary reagent strip used to estimate ten parameters including protein, glucose, and leukocytes. A diagnostic accuracy of each index test using corresponding cut-off levels (glucose 1 + vs. CSF glucose >50 mg/dL; protein 1 + and 2 + vs. CSF protein >30 mg/dL and >100 mg/dL; leukocyte esterase positivity vs. >10 granulocytes in CSF sample were done. A constructed Receiver Operating Curves (ROC) was used to evaluate overall performance of index tests and estimated Area Under the Curve (AUC).[9] A population based study shows that in Nova Scotia the Self Monitoring of Blood Glucose (SMBG) test strips claimed by the majority of seniors were within Canadian guidelines. However, a small proportion of beneficiaries claimed for SMBG test strips infrequently or too frequently, which suggests areas for improvement. [10]

Comparisons between the urine-testing and SMBG groups showed no significant differences in mean fasting plasma glucose (P >0.86), glycosylated hemoglobin (P>0.95), or weight (P> 0.19). In patients with T2DM not treated with insulin, SMBG is no more effective, but is 8-12 times more expensive, than urine testing in facilitating improved glycemic control and the results obtained do not support widespread use of SMBG in T2DM patients not treated with insulin.[11] Both Clinitest error and a variable relationship between arterial and urine glucose concentrations make the use of Clinitest as the sole monitor and basis for controlling blood glucose levels in critically ill patients as unsatisfactory and potentially dangerous procedure.[12] Among the commercial test papers, Tes-Tape, Clinistix, Uristix and Combistix, and the tablet preparation, Clinitest, was evaluated as indicators of glucose in urine by means of a quantitative automated glucose oxidase procedure for glucose determination. The semiquantitative Tes-Tape yielded very low values on urine specimens when compared with the quantitative method. More reliable results could be obtained with this product if the urine specimens were first treated with a mixed bed resin to remove inhibitors of the glucose oxidase peroxidase system. The qualitative test papers, Clinistix, Uristix and Combistix, yielded responses in closer agreement with the automated data, the best performance being obtained with Clinistix. The semiquantitative Clinitest tablets generally yielded more accurate results on a direct urine test than did Tes-Tape, although the Clinitest tablet is designed to measure total reducing substances rather than glucose alone.[13]

Ketone bodies, salicylic acid and several antibiotics do not influence the test strip. Ascorbic acid shows a slight influence only in concentrations above 40 mg/dL. This influence disappears with glucose concentrations > 500 mg/dL. Good correlation with the reference method, wide range of readings and simple handling make the test strip suited for the laboratory and particularly for self monitoring of diabetic patients.[14] Diabur-Test 5000 is a new semiquantitative test strip for the determination of urine glucose concentrations up to 5%. The results are comparable to those obtained with the Clinitest method, although Diabur-Test 5000 has the advantage of being sensitive for low glucose concentrations. Diabur-Test 5000 is easier to use than the Clinitest method. It is well accepted by patients for self monitoring, and might also be used for routine clinical work.[15] The new urine test, Chemstrip uG, was compared with Clinitest and Diastix methods on pediatric diabetic patients and by health care professionals. Chemstrip uG is a clinically useful and acceptable method for self-monitoring of urine glucose in diabetic children.[16]

Because many diabetics have blood glucose concentrations up to 200 mg/dL, it is advantageous if glucosuria up to 5% is detectable by routine home urine tests. The 2-drop Clinitest method detects glycosuria up to 5% without significant loss of accuracy and is recommended in preference to the 5-drop method.[17] Glucose concentrations in urine specimens passed at 7 am, 12 noon and 6 pm (home testing) were compared with blood glucose concentrations checked at the same times. Correlation was not very close. Correlation between pooled urine collections and 24 hour blood sugar profiles was equally poor. This suggests that urine sugar testing is unsatisfactory for home monitoring of children with diabetes and the results are inadequate for diagnostic or therapeutic purposes.[18] Diabur-Test 5000 proved to be superior to the well-known Clinitest-2-drop method ($p < 0.001$). In the hands of patients, this semiquantitative method proved to be somewhat less but still sufficiently precise to be recommended for urine glucose monitoring in diabetic children and adolescents.[19]

Material and Methods

250 patients attending the routine Master Health Checkup in the age group of 15-80 years consisting of males and female were selected for this study. The main aim of this study was to find out the correlation between plasma glucose measured by GOD-POD to urine glucose measured using multistix.

Dialab and DIRUI CS 1300B analyser was used to measure plasma glucose and DIURI H100 reflectance analyser and multistix marketed by the same company was used to measure urine glucose. The accuracy of all Plasma Glucose were validated by the use of Bio-Rad accuracy controls at two levels and Urine glucose by Dirui commercial quality control.

For Statistical analysis of data, a software downloaded from the website http:// www.vssarstats.com was used to calculate correlation coefficient (r), Student 't' distribution (t) and probability (p) between Plasma glucose and urine glucose.

Table I. Quantitative Comparison Statistical parameters (P. Glucose Vs U. Glucose)

Comparison	r	t	p
P. Glucose Vs U.Glucose by GOD POD	0.6550	13.651	<0.000001
U.Glucose (GOD POD) Vs U. Glucose (Mutlistrix)	0.6837	14.754	<0.000001
P. Glucose Vs U.Glucose (Multistix)	0.8415	24.529	<0.000001

Result

The mean plasma and urine glucose obtained for 250 patients in this study were 160 and 386 mg/dL respectively.

Table I presents the statistical data obtained for plasma and urine glucose. A highly significant correlation was obtained for all the three sets of comparison ($P<0.000001$) indicating that the multistix used to measure urine glucose is reliable and could be recommended for routine use to validate the relationship between a patients' plasma and urine glucose in the absences of kidney diseases.

Discussion

Generally in all diabetic patients, whenever plasma glucose exceeds the renal threshold of 180mg/dL, presence of glucose in urine is always detected in the absence of renal glycosuria. Several brands of test strips to detect sugar in urine are available but each brand has its merits and demerits.[4] Most test trips used in bed side either in hospital or at home is based on the qualitative observation of the presence of sugar in urine and reported as nil to several positives enabling the patients to roughly guide their glycemic level. Several studies have been done using cut off values to report urine glucose but this study has proved a very reliable quantitative relationship between plasma and urine glucose obtained using multistix.[11] In many previous studies no significant correlation have been established, but this study has established a highly significant correlation between plasma and urine glucose. [12,13,14]

Conclusion

The outcome of this study has confirmed that Diuri's multistix were found to give reasonably good results and the correlation between plasma glucose and urine glucose measured using multistix was highly significant, justifying that the results obtained for urine glucose using the multistix was indeed in agreement with plasma glucose. The outcome of this finding recommends that whenever a lab introduces a new brand of test strip, it is important to evaluate its performance for correlation agreement with plasma glucose.

Conflict of Interest : None

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