

Performance indicators and validity of serum fructosamine assay as a diagnostic test in a screening program for diabetes mellitus

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ABSTRACT

Objectives: To evaluate the performance indicators and validity of fructosamine assay as a diagnostic tool in screening for Diabetes mellitus (DM).

Methods: Fasting plasma glucose (FPG) and serum fructosamine (FA) were compared in 1015 subjects aged ≥ 25 years from different urban and rural areas in Mosul city, Northern Iraq. The subjects were classified into 5 groups: Group 1: Subjects with FPG < 6.1 mmol/L (n=883), Group 2: Subjects with impaired FPG 6.1-6.9 mmol/L (n=29), Group 3: New diabetics diagnosed solely by new 1997 American Diabetes Association (ADA) criteria with FPG 7.0-7.7 mmol/L (n=20), Group 4: New diabetics diagnosed according to old 1980-1985 World Health Organization (WHO) criteria with FPG ≥ 7.8 mmol/L (n=23), and Group 5: Known diabetics (n=60). Subjects in groups 2 and 3 underwent a standard 75 gm oral glucose tolerance test (OGTT) as recommended by the WHO. Reclassification of subjects into 3 groups according to FPG or 2hPG, or both was carried out for all subjects. Group A (non-diabetics): Subjects with FPG < 6.1 mmol/L or 2hPG < 7.8 mmol/L, or both (n=910). Group B (Diabetics): Subjects with FPG ≥ 7.8 mmol/L or 2hPG ≥ 11.1 mmol/L, or both (n=92) including 60 known diabetics in group 5 and 23 new diabetics in group 4 in addition to 2 subjects in group 2 and 7 subjects in group 3. Group C (impaired glucose tolerance, IGT): Subjects with 2hPG between 7.8-11.1 mmol/L (n=13).

Results: Having all subjects had their serum FA being measured; the Receiver Operator Characteristic (ROC) curve

was constructed on the data to determine the trade off between sensitivity and specificity of the FA test in the diagnosis of DM. This construction decided that serum FA value of 2.65 mmol/L would be the cutoff point, or the positivity criterion in the calculation of the validity parameters of FA test. Of 910 non-diabetics, 886 subjects had measured FA values within the 95th percentile, while 24 had FA higher than the cutoff point. Consequently, FA in non-diabetics yielded 886 (true negatives) and 24 (false positives). Of the 92 diabetics, 30 subjects had normal FA values, while 62 diabetics showed FA higher than the cutoff point. Consequently, FA in diabetics yielded 30 (false negatives) and 62 (true positives). Accordingly, the sensitivity, specificity, positive predictive value, negative predictive value, accuracy rate, positive likelihood ratio and negative likelihood ratio were 67.3%, 97.3%, 72.3%, 96.7%, 94.6%, 26 and 2.99. A highly significant correlation was observed between FPG and measured FA in non-diabetics ($r=0.85$, $p<0.0001$) and diabetics ($r=0.92$, $p<0.0001$). No significant correlation was observed between serum FA and albumin in non-diabetics ($r=0.14$, $p>0.05$) and diabetics ($r=0.08$, $p>0.05$).

Conclusion: Fructosamine test shows a moderate sensitivity with a high specificity as a diagnostic test for diabetes mellitus. The considerable overlap between diabetics and non-diabetics limit its usefulness. It is recommended that fructosamine test is not a suitable screening test for the disease. Measurement of plasma glucose (fasting or post-OGTT) remains the corner stone as a diagnostic test.

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Diabetes mellitus (DM) is, by far, the most common of the endocrine disorders that affect humans. It has been reported in almost all populations of the world with variable prevalence rates in different countries.¹ The screening tests for type 2 DM includes measurement of plasma glucose in fasting or postprandial state with or without detection of glucose in urine. Measurement of glycated hemoglobin (HbA1c) or glycated serum protein has a growing role in the assessment of glycemic control but their use for screening purpose is questionable. The sensitivity and positive predictive value (PPV) of all these tests depend on the cutoff point of these indices.² Screening for DM in asymptomatic adults suffers from 2 important limitations: the lack of a practical screening test that is both sensitive and specific, and insufficient evidence that detection of diabetes in the asymptomatic period significantly improves long-term outcome.³

Fructosamine (FA) is the trivial name of 1-amino-1-deoxy-fructose, also called isoglucoamine by Emil Fischer, who first synthesized the compound in 1886.⁴ More broadly, FA is a ketoamine that arises from a post-translational modification through Amadori rearrangement process involving a non-enzymatic condensation of a sugar (usually glucose) and a protein (usually albumin).⁵⁻⁷ Johnson et al⁸ in 1983 described a novel colorimetric assay for the determination of serum FA based on the reducing ability of ketoamine in alkaline buffer. Measurement of serum FA represents an intermediate index of glycaemic state during the proceeding 2-3 weeks. This is a reflection of the biological life of albumin (21 days) and other proteins (2.5-23 days).^{5,9} Its concentration will change more rapidly than those of glycated hemoglobin, which can alert physicians to deteriorating control before changes in glycated haemoglobin can be detected.⁵ Many studies have revealed that serum FA correlates significantly with mean plasma glucose and so presents a suitable index for the evaluation and monitoring of glycaemic control particularly in those with unstable diabetes.¹⁰⁻¹² These metabolic indices: glucose, HbA1c or FA reflects the glycaemic state over different periods. Measurement of plasma glucose has an established role in the diagnosis as well as assessment of short-term glycaemic control.³ On the other hand, measurement of glycated indices, HbA1c or FA, have wide spread value mainly in the assessment of metabolic control.^{5,13} In addition, there is a growing evidence for their additional value as diagnostic tests for DM.^{10,14-16}

The aim of this study was to assess the performance indicators and validity of fructosamine assay as a screening test for the diagnosis of Diabetes mellitus. Both, the 1980-1985 criteria of the World Health Organization (WHO) and the 1997 criteria of the American Diabetes Association (ADA) based on fasting plasma glucose or 2-hour plasma glucose following 75g oral glucose load were used as the gold standard for the establishment of the diagnosis.

Methods. This study represents a cross-sectional survey of DM. The survey program involved screening of the disease among a population sample of 1015 subjects aged ≥ 25 years. The population screened consisted of 3 samples. The first sample was composed of 489 subjects (223 males and 266 females) from 100 households among the residents of Al-kahira quarter which lies to the left side of Tigris River in the eastern part of Mosul city, Northern Iraq with a total population of 12498. The subjects were randomly chosen. They were informed about the survey with all subjects being examined were asked to fast overnight before the test performance when they were visited in the proceeding day. The second sample was composed of 200 subjects (94 males and 106 females) from 49 households among the residents of Al-Sherikhan village, which lies 17 Km to the northwest of Mosul center on the left side of Tigris River. These subjects were volunteered to be screened for DM during their participation in the annual community-based survey study conducted by the University of Mosul during the period from 14th-21st September 2000. The village is comprised of 560 households with a total population of 4000. The community was informed of the survey with all subjects were asked to fast before the test when they were visited a day before. The third sample was composed of 326 subjects (65 males and 261 females). They represented the relatives of the patients admitted to Al-Khansaa Maternity Hospital in Northern Mosul. They were asked to fast before the test when they were visited on the proceeding day. A complete record of every subject's history was obtained including name, age, sex, residence, occupation, family history of diabetes and the past medical history of the subject and his/her family. The subjects from the 3 samples who were discovered to have been known or diagnosed diabetics (N=60) were instructed to fast overnight and venous blood samples were then collected in the next morning.

Classification according to fasting plasma glucose. Classification of all subjects was first carried out according to fasting plasma glucose (FPG) level utilizing both the 1997 criteria of the ADA¹⁶ (new criteria), and the 1980-1985 criteria of the WHO¹⁷ old criteria). The subjects were classified into the following 5 groups: Group 1: Subjects with normal FPG of < 6.1 mmol/L. Group 2: Subjects with impaired fasting glucose (IFG) having FPG of 6.1-6.9 mmol/L. Group 3: Diabetics solely by new ADA criteria with FPG of 7.0-7.7 mmol/L. Group 4: Diabetics by new ADA and old WHO criteria with FPG ≥ 7.8 mmol/L. Group 5: Known (diagnosed) diabetics.

Classification according to post challenge plasma glucose. The 2nd classification was carried according to WHO criteria using both FPG and 2 hours plasma glucose (2hPG) values following oral glucose tolerance test (OGTT). Subjects in group 2 (IFG) and group 3 (diabetes solely by the new FPG criteria) were informed

of the test and their need for this glucose challenge procedure the day before the test. On the examination day, a fasting venous blood sample was collected, then 75 gm anhydrous glucose dissolved in 250-300 ml water was given orally and a 2nd blood sample was collected after 2 hours. The subjects were classified into the following 3 groups: Group A: Non-diabetics. This group included subjects with FPG < 6.1 mmol/L or 2hPG < 7.8 mmol/L. Group B: Diabetics. This group included subjects with FPG \geq 7.8 mmol/L or 2hPG \geq 11.1 mmol/L following OGTT, in addition to known (diagnosed) diabetics. Group C: Impaired Glucose Tolerance (IGT). This group included subjects who had 2hPG values ranged from 7.8-11.1 mmol/L following OGTT. Blood samples were obtained from all subjects by antecubital venepuncture between 8.00-10.00 am during a period of 6 months from August 2000 through to January 2001. All subjects were instructed to fast overnight for 8-12 hours, and this fasting state was confirmed by them before blood collection. About 4 ml of blood specimen was taken and divided into 2 parts, each was treated as follows: 1. For the measurement of glucose concentration; 2ml of blood was collected and mixed in a tube containing the glycolytic inhibitor sodium fluoride and potassium oxalate, then separated by centrifugation at 3000 rpm into plasma within 3 hours. 2. For the measurement of other biochemical parameters (FA and albumin), the remaining 2 ml of blood was collected in plain tube, allowed to clot then separated into serum by centrifugation at 3000 rpm.

Plasma glucose was estimated by glucose oxidase-peroxidase method,¹⁸ using a kit supplied by Randox (England). Serum FA was measured manually using nitroblue tetrazolium colorimetric method.⁸ Serum albumin was determined by bromocresol green (BCG) dye binding method¹⁸ using a kit purchased from Randox (England). Calculation of corrected fructosamine (according to albumin concentration) is carried out according to the formula recommended by Howey et al¹⁹: FA (c) = FA (m) + 0.03 (40 - Albumin concentration g/l) where FA (c): corrected fructosamine, FA (m): measured fructosamine.

Performance indicators and validity of fructosamine assay. The validity of a test is reflected by its ability to distinguish between an individual who has a disease and who does not.²⁰ Any test has to have the following indicators to be evaluated: 1. Validity indicators; which include: a. Sensitivity and specificity. b. Trade-off between sensitivity and specificity. 2. Positive predictive value (PPV) and negative predictive value (NPV). 3. Accuracy rate. 4. Likelihood ratio (positive and negative). Deciding a cutoff point between normal and abnormal values requires a tradeoff between sensitivity and specificity. To express this relationship, the true positive rate (sensitivity) has to be plotted against false positive rate (1-specificity) constructing a curve called the Receiver Operator Characteristic (ROC) Curve. This curve may identify the desirable diagnostic cutoff point or positively criterion that separates the normal from

abnormal. It represents the highest attainable sensitivity before specificity starts to deteriorate rapidly.²⁰

Standard statistical methods were used to determine the mean, median, standard deviation (SD) and range. The Paired student Z-test was used to compare results for various biochemical parameters among subjects of the same group. The Unpaired student Z-test was also used to compare results for various biochemical parameters among subjects in different groups. All values quoted as the mean \pm SD. Differences between observations were considered significant at $p < 0.05$.²¹

Results. Diabetes mellitus was defined according to the 1980-1985 WHO criteria,¹⁴ for example FPG \geq 7.8 mmol/L and 2hPG \geq 11.1 mmol/L for diabetes or both, 2hPG \geq 7.8 mmol/L but < 11.1 mmol/L for IGT and 2hPG < 7.8 mmol/L for non-diabetics. Following OGTT, 2 subjects (6.9%) in group 2 and 7 subjects (35%) in group 3 had 2hPG \geq 11.1 mmol/L and considered to be diabetics. Six subjects (20.7%) in group 2 and 7 subjects (35%) in group 3 had 2hPG between 7.8-11.1 mmol/L and considered having IGT. Twenty-one subjects (72.4%) in group 2 and 6 subjects (30%) in group 3 had 2hPG < 7.8 mmol/L and considered to be non-diabetics. In other words, a state of DM or IGT was noted in 8 subjects (27.6%) in group 2 (with FPG 6.1-6.9 mmol/L) and in 14 subjects (70%) in group 3 (with FPG between 7.0-7.7 mmol/L). Regrouping of subjects was then carried out according to the 1980-1985 WHO criteria based on the results of FPG and OGTT. The new groups A, B and C are described as follows:

Group-A: Non-diabetics. This group constituted non-diabetic subjects with FPG < 6.1 mmol/L or 2hPG < 7.8 mmol/L following OGTT. It was composed of 910 subjects (567 females and 343 males) including 883 subjects from group one with normal FPG (<6.1 mmol/L), 21 subjects from group 2 with IFG (6.1-6.9 mmol/L) and 6 subjects from group 3 with (FPG 7.0-7.7 mmol/L). All subjects from groups 2 and 3 had 2hPG < 7.8 mmol/L. The mean \pm SD of FPG of this group was 4.87 \pm 0.75 mmol/L. The mean \pm SD of FAm of this group was 1.98 \pm 0.34 mmol/L with the median of 1.98 mmol/L. For FAc, the mean \pm SD of group A was 1.89 \pm 0.36 mmol/L with the median 1.88 mmol/L.

Group-B: Diabetics. This group included new diabetics with FPG \geq 7.8 mmol/L or 2hPG \geq 11.1 mmol/L in addition to the old (known) diabetics with already diagnosed diabetes. It was composed of 92 subjects (60 females and 32 males) including 60 known diabetics (group 5) and 32 newly diagnosed diabetics of whom, 9 subjects (2 from group 2 and 7 from group 3) with 2hPG \geq 11.1 mmol/L, in addition to 23 subjects who formed group 4 with FPG \geq 7.8 mmol/L. Among all these diabetics, the mean \pm SD of FPG was 10.09 \pm 3.22 mmol/L and the median was 9.25 mmol/L. The mean \pm SD of FAm was 2.88 \pm 0.73 mmol/L (range 1.30-6.73 mmol/L) and median was 2.84 mmol/L. Mean \pm SD of FAc in this group was 2.86 \pm 0.73 mmol/L (range 1.15-

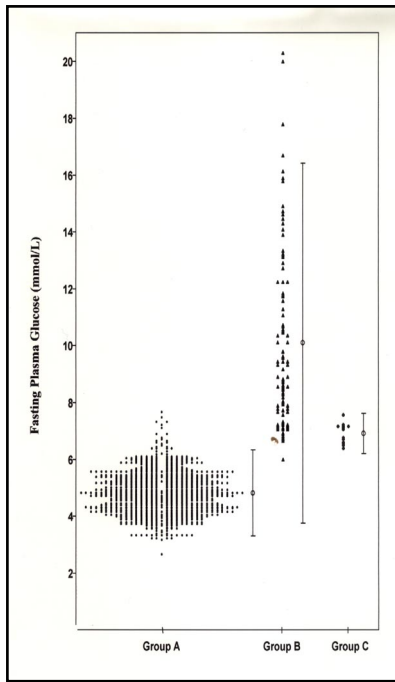


Figure 1 - Distribution of fasting plasma glucose in non-diabetics (group A), diabetics (group B) and subjects with impaired glucose tolerance (group C). Bars represent mean \pm 2SD.

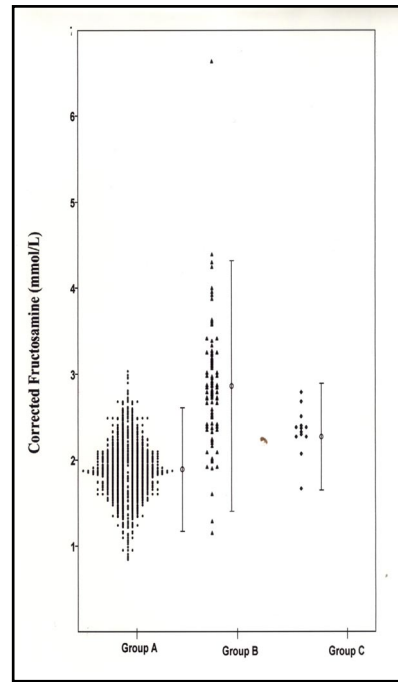


Figure 3 - Distribution of corrected serum fructosamine in non-diabetics (group A), diabetics (group B) and subjects with impaired glucose tolerance (group B). Bars represent mean \pm 2SD.

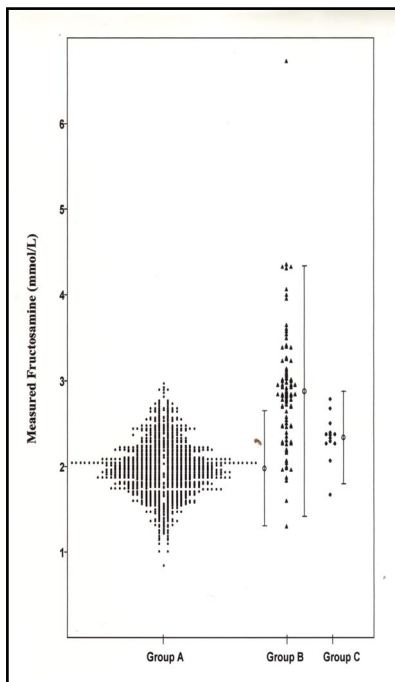


Figure 2 - Distribution of measured serum fructosamine in non-diabetics (group A), diabetics (group B) and subjects with impaired glucose tolerance (group C). Bars represent mean \pm 2 SD.

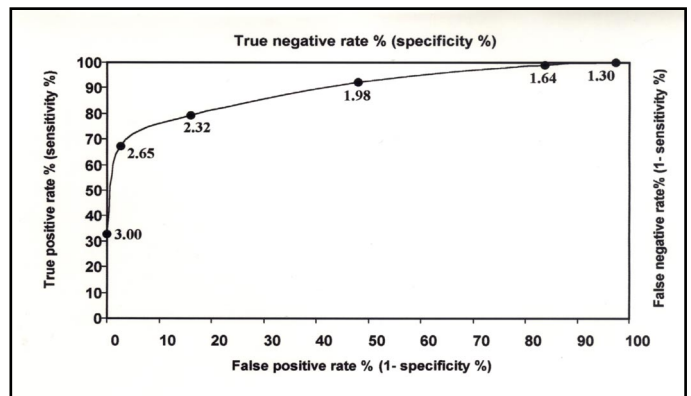


Figure 4 - Receiver Operate Characteristic (ROC) curve for the positivity criterion of serum fructosamine assay. Values of fructosamine on the curve are expressed in mmol/L.

6.64 mmol/L) with a median of 2.81 mmol/L. When the unpaired student Z-test was used to compare values of FPG, measured and corrected FA in group A and B, it revealed a highly significant difference between the 2 groups for each of these parameters where $Z=15.45$ ($p < 0.0001$) for FPG, $Z=12.76$ ($p < 0.0001$) for FAm and $Z = 13.06$ ($p < 0.0001$) for FAc.

Group C: Impaired glucose tolerance. This group constituted 13 subjects (6 females and 7 males) who exhibited an intermediate metabolic response to the OGTT with 2hPG values ranged between 7.8-11.1 mmol/L. The mean \pm SD of FPG was 6.89 ± 0.35 mmol/L with the mean \pm SD of 2hPG was 9.17 ± 0.58 mmol/L. The mean \pm SD of FAm was 2.34 ± 0.27 mmol/L (range 1.67-2.79 mmol/L) and of FAc was 2.27 ± 0.30 (range 1.64-2.73 mmol/L). The mean \pm SD of serum albumin was 42.1 ± 5 (range 36-55 g/l). The frequency distributions of FPG, FAm and FAc in group A-C are shown in **Figures 1, 2 & 3**. In addition, the results of FPG, FAm, FAc and albumin in these groups are presented as in **Table 1**.

Performance indicators for the validity of serum fructosamine as a screening test for the diagnosis of diabetes mellitus. The performance of FA assay as a diagnostic test for DM was evaluated at various cutoff points (the points corresponded to: mean -2 SD, mean -1 SD, mean, mean $+1$ SD, mean $+2$ SD and mean $+3$ SD)

to illustrate the tradeoff between the test sensitivity and specificity at each cutoff point level. **Table 2** exhibits the tradeoff between sensitivity and specificity of the test and it shows that when the sensitivity increases, the specificity decreases.

According to the relation between the sensitivity and the specificity, the ROC curve was constructed for FAm test in order to select the diagnostic cut off point or the positivity criterion for the test in the diagnosis of DM, **Figure 4**. The diagnostic cutoff point is the point on the curve, which is nearer to the upper left-hand corner of the curve. In case of FAm, it almost corresponds to 2.65 mmol/L which also represents the value of the mean $+2$ SD and it would be the point to separate normal FA (negative result) from abnormal (positive result). This cutoff point was used to calculate the various validity indicators.

Using the cutoff point of FAm of 2.65 mmol/L, 62 diabetics had FAm higher than the cutoff point and they represented (true positives), while the other 30 diabetics had FAm values lower than the value of the positivity criterion and thus considered as (false negatives). On the other hand, 886 non-diabetics exhibited negative FAm test results (≤ 2.65 mmol/L) and considered as (true negatives). The remaining 24 non-diabetics had elevated FAm (>2.65 mmol/L) and represented (false positives), **Table 3**. The performance and validity indicators were calculated as the following (see below).

$$\text{Sensitivity} = \frac{\text{true positives}}{\text{true positives} + \text{false negatives}} \times 100 = 67.3\%$$

$$\text{Specificity} = \frac{\text{true negatives}}{\text{true negatives} + \text{false positives}} \times 100 = 97.3\%$$

$$\text{Positive predictive value (PPV)} = \frac{\text{true positives}}{\text{true positives} + \text{false positives}} \times 100 = 72.1\%$$

$$\text{Negative predictive value (NPV)} = \frac{\text{true negatives}}{\text{true negatives} + \text{false negatives}} \times 100 = 96.7\%$$

$$\text{Accuracy rate} = \frac{\text{true positives} + \text{true negatives}}{\text{total}} \times 100 = 94.6\%$$

$$\text{Positive likelihood ratio} = \frac{\text{true positives}}{\text{true positives} + \text{false negatives}} \div \frac{\text{false positives}}{\text{false positives} + \text{true negatives}} = 26$$

$$\text{Negative likelihood ratio} = \frac{\text{true negatives}}{\text{true negatives} + \text{false positives}} \div \frac{\text{false negatives}}{\text{false negatives} + \text{true positives}} = 26$$

Table 1 - Mean \pm standard deviation of fasting plasma glucose, fructosamine (measured and corrected) and albumin in non-diabetics (group A), diabetics (group B) and subjects with impaired glucose tolerance (group C).

Group	FPG (mmol/L)	FAm (mmol/L)	FAc (mmol/L)	Albumin (g/L)
A	4.82 \pm 0.75	1.8 \pm 0.335	1.89 \pm 0.360	43.3 \pm 5.160
B	10.09 \pm 3.22	2.88 \pm 0.73	2.86 \pm 0.730	41.0 \pm 5.220
C	6.92 \pm 0.35	2.34 \pm 0.27	2.27 \pm 0.310	42.1 \pm 4.910

FPG - fasting plasma glucose, FAm - serum measured fructosamine
FAc - serum corrected fructosamine

Table 2 - Trade off between sensitivity and specificity in 910 non-diabetics and 92 diabetics using serum fructosamine assay as a diagnostic test.

FAm mmol/L	Sensitivity % (True positives)	Specificity % (True negatives)
3.00 (mean \pm 3 SD)	32.6	100
2.65 (mean \pm 2 SD)	67.3	97.3
3.32 (mean \pm 1 SD)	79.4	84
1.98 (mean)	92.4	52
1.64 (mean - 1SD)	98.9	16.3
1.30 (mean - 2SD)	100	2.6

FAm - serum measured fructosamine
SD - standard deviation

Table 3 - Comparison between serum fructosamine and plasma glucose (fasting or 2hPG) according to the World Health Organization criteria as screening tests for diabetes mellitus.

Fructosamine >2.65 mmol/L	FPG \geq 7.8 mmol/L or 2hPG \geq 11.1 mmol/L		
	Positive	Negative	Total
Positive	62	24	86
Negative	30	886	916
Total	92	910	1002

FPG - fasting plasma glucose

These findings mean that FA test has the ability to correctly identify 67.3% of those truly have DM and the ability to give a negative result in 97.3% of those truly free from the disease. The probability of having DM using FA test when its result is positive is 72.1%, however, the probability of not having the disease is 96.7% when it is negative. The positive FA result is 26 times more likely to occur in diabetics than in normal subjects and the negative FA result is 2.99 times more likely to occur in non-diabetics than in diabetics, however, the test is characterized by a high accuracy rate of 94.6%.

Discussion. A major advance in diabetic care has been developed when glycated hemoglobin and glycated serum protein established their role as indices of glycemic control in the last 20 years.²² Different methodologies are available with different working steps and reference ranges.²³ The development of a novel method for the measurement of serum FA has gained wide spread application in diabetic care since its introduction by Johnson et al.⁸ Currently, achievement of proper glycemic control has to include measurement of at least one of the glycated proteins.

The most commonly used screening test includes measurement of plasma glucose in fasting or post prandial state.² This study evaluates the performance of serum FA assay as a screening test for the diagnosis of DM in Mosul city, Northern Iraq among the general population including both high and low risk subjects. When diabetic subjects were compared with non-diabetics, the diabetics had higher FPG values with a significant difference between the 2 groups ($Z=15.45$, $p < 0.0001$), and higher serum FA values with a significant difference in mean FAm and FAc ($Z=12.76$, $p < 0.0001$, and $Z=13.06$, $p < 0.0001$). These findings are comparable with the results provided by other workers who also demonstrated a significant difference in FA concentration between diabetics and non-diabetics.^{5,24} However, the considerable overlap in FA values between diabetics and non-diabetics may limit its usefulness as a diagnostic test. This makes FA test a complementary tool in distinguishing non-diabetics from diabetics particularly when high values are obtained. Measurement of HbA1c or serum FA have been suggested as a screening tool for DM including GDM by many workers.²⁵⁻²⁸ To assess such a utility, the performance indicators of FA test were evaluated in the current study and the tradeoff between sensitivity and specificity was determined through constructing ROC curve. The sensitivity, specificity, PPV, NPV, accuracy rate, positive likelihood ratio and negative likelihood ratio were 67.3%, 97.3%, 72.1%, 96.7%, 94.6%, 26 and 2.99. These findings mean that although the test is highly specific (does not label more than 3% as diabetics when they are normal), it is of moderate sensitivity (misclassify 33% of diabetics as non-diabetics) which leads them to be exposed to the high risk of future complications due to missing diagnosis.

The high true negative rate of the test among non-diabetics would make a high NPV, which indicates that the probability of any subject to be a non-diabetic when the result of the test is negative is 96.7%. The lower true positive rate (in comparison to the true negative rate) would make the probability of any subject to be diabetic using this test, when its result is positive, is not more than 72.1%. However, the data show a high accuracy rate for FA test of 94.6%, which is also evident by the large area below ROC curve.

Comparable results were reported by Salemans et al²⁹ who screened 183 subjects suspected of DM using FA assay. They found sensitivity and specificity rates of 67% and 96% with positive and NPV of 79% and 93%. Comparable results were also observed by Baker et al¹⁰ who found FA assay to have a 0.75 probability of true diagnosis in 74 patients referred for an OGTT. Lloyd and Marples,²⁴ using the FA test for the diagnosis of DM, detected 25 subjects out of 30 untreated diabetics with the test yielded 4 false positives (8%) from a total of 50 non-diabetic subjects, giving rise to test sensitivity and specificity of 84% and 92%. Also, when FA assay was used to screen 167 pregnant women for GDM, it gave a sensitivity of 86% and a specificity of 95%.²⁶ The different figures of validity indicators of FA test as screening test for DM obtained from different studies may be attributed to many causes. These include the difference in the number of subjects being screened (population sample size) and among others, is the different severity and prevalence of DM in different populations.

To determine the efficiency of HbA1c and FA as alternatives to FPG for screening of diabetes, ROC was constructed on the three tests in a study consisted of 583 non-diabetics and 36 diabetics.³⁰ The results showed that the area under curve of HbA1c was not different from that of FPG, while that of FA was significantly smaller making a conclusion that HbA1c is a good alternative to FPG while FA is not suitable for screening of DM. These findings rose suspicion regarding the possible improvement in the performance indicators of screening tools of DM if used together.

A recent study³¹ tested the combined use of FPG and HbA1c or FA to predict the likelihood of having diabetes in high-risk subjects, where 2877 men and 2312 women with various risk factors of diabetes (like obesity, positive family history and IGT) underwent OGTT. It was concluded that the paired use of FPG and HbA1c or FPG and FA helped to identify potentially diabetic subjects, the diagnosis of which could be further confirmed by OGTT.

In conclusion, the fructosamine test shows a moderate sensitivity with a high specificity as a diagnostic test for Diabetes mellitus. The considerable overlap between diabetics and non-diabetics limits its usefulness for this purpose. It is recommended that fructosamine test is not a suitable screening test for the disease. Measurement of

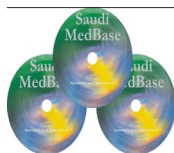
plasma glucose (fasting or post-OGTT) remains the corner stone as a diagnostic test.

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Related Abstract
Source: Saudi MedBase



Saudi MedBase CD-ROM contains all medical literature published in all medical journals in the Kingdom of Saudi Arabia. This is an electronic format with a massive database file containing useful medical facts that can be used for reference. Saudi Medbase is a prime selection of abstracts that are useful in clinical practice and in writing papers for publication.

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Abstract

Objectives: This study was initiated to determine the prevalence of diabetes mellitus and impaired glucose tolerance (IGT) in the childhood and adult populations in 7 different areas in the Kingdom of Saudi Arabia.

Methods: A household survey was conducted, fasting and 2-hour 'post-glucose load' blood samples were collected from 6368 Saudi males and females and the blood glucose level was estimated. The diagnosis of diabetes mellitus and IGT was based on the criteria of the World Health Organization.

Results: The overall prevalence of insulin-dependent diabetes mellitus (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM) in the total population was 1% and 4.25%. The prevalence of NIDDM in females (4.7%) was higher than in males (3.7%), however, the difference was not statistically significant. Children (≤ 14 years) were separated from adults and the prevalence was calculated in adult males, females and children. The prevalence of NIDDM increased to 6.2% and 7.2% in adult males and females. Prevalence of IDDM was higher in children (1.55%) than adults (0.6%). Impaired glucose tolerance was identified at a higher prevalence in adult males (1.7%) than females (1.1%). Differences were encountered in the prevalence of diabetes in the different regions of the country.

Conclusion: The Saudi population can be regarded as a moderate risk population for diabetes mellitus. It is suggested that steps must be taken to improve awareness of the disease and to take measures towards prevention and control of this syndrome.