

Should screening voluntary blood donors be used as strategy to diagnose diabetes and diabetic nephropathy?

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ABSTRACT

Introduction and Aim: The present study aims to assess the glycemc status during voluntary blood donation as a strategy to detect undiagnosed diabetes mellitus and diabetic nephropathy. **Material and Method:** Study was conducted at a tertiary care hospital and medical college. All voluntary blood donors underwent random capillary blood glucose screening and patients who had random blood sugar exceeding 200 mg/dl were subjected to undergo oral glucose tolerance test (OGTT). The subjects thus detected diabetic by capillary blood sugar and OGTT underwent screening diabetic kidney disease with urine albumin to creatinine ratio (UACR). Data collected was statistically analyzed using SPSS 16 using Student's t test. **Results:** Seven hundred and sixty five males and 443 females were enrolled for the study. Capillary blood sugar of 54 subjects was ≥ 200 mg/dl. 48 subjects gave consent for OGTT, stratified data showed 22 subjects (12 males and 10 females) were in range of 200–300 mg/dl. 20 subjects (12 males and 8 females) were in range of 300–400 mg/dl, whereas 6 subjects (5 males and 1 female) had blood sugar more than 400 mg/dl. The HbA1C ranges in respective glycemc groups were 200–300 mg/dl – 7.4% to 8.6% (mean – 8.05%), 300–400 mg/dl – 8.7% to 11.8% (mean 9.63%), more than 400 mg/dl – 11.8% to 14.2% (mean – 13%). Male preponderance was observed in all glycemc groups, though the difference was statistically insignificant. Of the 48 diabetic subjects, 13 (27.08%) were detected to have albuminuria, of these 11 (22.91%) had microalbuminuria (UACR 30 – 300 mg/gm), whereas 2 (4.16%) had overt proteinuria (UACR exceeding 300 mg/gm). **Conclusion:** Glycemc screening with random capillary blood glucose screening, 75 gm 2 hour OGTT and HbA1C amongst voluntary blood donors can be used to detect pre diabetes and undiagnosed diabetes mellitus and diabetic nephropathy.

Keywords: Blood glucose, diabetes mellitus, diabetic nephropathy

Introduction

India has the second largest diabetic population globally with 69.2 million affected individuals.^[1] India also has the largest regional cause of mortality attributable to diabetes.^[2] Rapid urbanization, changing food habits, and sedentary lifestyle are contributory to this epidemic. Undiagnosed diabetes mellitus accounts for 10% (592 million adults) of all diabetics in India^[3], and various studies (Joshi *et al.*, Raja *et al.*) have reported the

prevalence of undetected diabetes mellitus from 7.2% to 11.1%.^[4,5] Amongst the rural population, in a study amongst 4,535 individuals of rural Godavari region 13.2% were detected diabetic, of which 6.4% were known and 6.8% were undiagnosed diabetics.^[6] Early detection of diabetes leads to reduction in lead time between onset and clinical diagnosis and thus allows prompt multi factorial treatment of the same.^[7] Screening of voluntary blood donors for diabetes appears to be a promising strategy for the detection of diabetes in population at large. Voluntary blood donation accounts for the major source of blood (components) to blood banks in India. This study aims to assess the prevalence of diabetes in voluntary blood donors and compares the data with other population screening studies.

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Received: 07-02-2020

Revised: 13-03-2020

Accepted: 07-04-2020

Published: 30-07-2020

Access this article online

Quick Response Code:



Website:
www.jfmpc.com

DOI:
10.4103/jfmpc.jfmpc_229_20

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How to cite this article: Agarwal P, Gautam A, Pursnani N, Jain A, Singh N, Singh B, *et al.* Should screening voluntary blood donors be used as strategy to diagnose diabetes and diabetic nephropathy? J Family Med Prim Care 2020;9:3582-5.

Material and Method

Selection of subjects

Subjects for the study were selected from the voluntary blood donors of blood bank facility at S. N. Medical College, Agra, Uttar Pradesh, India from Aug, 2018 to Nov, 2018.

In this cohort study, voluntary blood donors of both genders, from 25 years to 55 years were included. The subjects did not report any history of diabetes mellitus. The protocol was approved by the ethical committee of the hospital and donor selection complied with rules laid in drugs and cosmetics act 1940 (and subsequent amendments). Subjects were informed about the protocol of the investigation and informed consent was taken from the subjects.

Random capillary blood sugar screening

For donors who agreed for diabetes screening, random capillary blood sugar measurement (RCBS) was done with glucometer (accucheck active™ Johnson and Johnson inc.). Donors with RCBS of more than 200 mg/dl were given appointment for oral glucose tolerance test (OGTT) and HbA1C testing.

Oral glucose tolerance test (OGTT)

OGTT was performed on an empty stomach where donors were instructed to fast for at least 8 hours. After a blood sample was taken in the fasting state, the respective donors were given a 75 g oral glucose drink. Another blood sample was taken 2 hours after the glucose drink.

Glycosylated hemoglobin (HbA1C)

All subjects with RCBS exceeding 200 mg/dl underwent HbA1C testing using Alere Afinion™ AS100 multianalyzer.

Urine protein to albumin ratio (UACR)

All the subjects who had RCBS more than 200 mg/dl underwent urine albumin to creatinine ratio testing, where urine microalbumin was tested by quantitative turbidimetric assay (microalbumin turbilatex™). Urine creatinine was calculated by ERBA™ fully automatic analyzer.

Statistical analysis

All the experimental observations were done in replicates and mean value was evaluated. Student's t test was used for the analysis of categorical data. $P < 0.05$ was taken as significant.

Results and Discussion

Among the blood donor volunteers total 1,208 subjects of both genders were selected for the study. Their demographic distribution is given in Table 1.

Among the selected population 765 males and 443 females were enrolled for the study. Most of subjects (532) were of 35–44 years,

followed by 453 subjects of age group 25–34 years, least no of donors 223 were of age group 45–55 years. There is no significant difference among the population, in between the genders.

Random capillary blood sugar screening

Subjects were screened for the Random capillary blood sugar and observation was done and data is represented as in Table 2.

From the observation it was found that among 1208 subjects 54 were found to have blood sugar level above ≥ 200 mg/dl. Age stratified data showed 32 (45–55 years), 18 (35– 44 years), and 8 (25–34 years). These subjects were advised to attend diabetes clinic for further evaluation. Of these 6 people did not give consent for further evaluation and investigations.

Oral glucose tolerance test

48 Subjects (29 males and 19 females) underwent Oral Glucose Tolerance Test and results observed are tabulated as:

Glycemic stratification of OGTT participants was, 22 subjects (12 males and 10 females) in range of 200–300 mg/dl, 20 subjects (12 males and 8 females) with glucose level 300–400 mg/dl and 6 subjects (5 Males and 1 females) had glucose level > 400 mg/dl. From the observations of the studies it can be stated that volunteer blood donation serves a substantive tool for the early diagnosis of the diabetes [Table 3].

Glycosylated hemoglobin testing (HbA1C)

The HbA1C ranges in respective glycemic groups were 200–300 mg/dl – 7.4% to 8.6% (mean – 8.05%),

Table 1: Demographic distribution of the subjects

Age	Males	Females	Total
25-34	240	213	453
35-44	352	180	532
45-55	173	50	223
Total	765	443	1208

$P > 0.05$, not significant

Table 2: Results of RCBS of all the subjects

Blood sugar check RBSS	No. of subjects	Percentage $n=1208$
< 200 mg/dl	1154	95.53
≥ 200 mg/dl	54	4.47
	Age Group	Individual Percentage $n=54$
	25-34 years	7.40%
	35-44 years	33.33%
	45-55 years	59.25%

Table 3: HbA1C range in glycemic groups

No of subjects	OGTT range (mg/dl)	HbA1C range%	Mean HbA1C%
22	200- 00	7.4-8.6	8.05
20	300-400	8.7-11.8	9.63
06	> 400	11.8-14.2	13.0

300–400 mg/dl –8.7% to 11.8% (mean 9.63%), more than 400 mg/dl – 11.8% to 14.2% (mean – 13%).

The presence of impaired blood glucose level (RCBS >200 mg/dl) was 4.47%, whereas the presence of diabetes mellitus was 3.97%. Statistically insignificant male preponderance was observed in all glycemic groups.

Urine albumin to creatinine ratio (UACR) amongst blood donors who were detected as diabetics was conducted. The data showed that amongst the subjects who were detected diabetics, 13 (27.08%) were detected to have albuminuria, of these 11 (22.91%) had microalbuminuria (UACR 30–300 mg/gm), whereas 2 (4.16%) had overt proteinuria (UACR exceeding 300 mg/gm). The severity of glycemia correlated with degree of albuminuria and this correlation was significant amongst patients in severe hyperglycemia subgroups (HbA1C 8.7–11.8, 11.8–14.2).

The mean HbA1c and UACR values are compared using linear regression to evaluate if the relationship between these two variables exists. From the statistical analysis it was found that goodness fit value of both variables studied was 0.95 and 0.91 respectively and *P* value calculated as 0.12 and 0.18 (*P* > 0.05). This shows the linear relationship between the HbA1c and UACR value in diabetic patients.

Discussion

In the selected population most of the subjects 240 males and 213 females were of the age group 25–34 years, which resembles the study done by to J. Ramasamy *et al.*, and reported 112 subjects form the age group 18–28 years. Males preponderance was observed in blood donation volunteer ship in both the studies.^[8]

In the present study 54 subjects who did not had any test for sugar level and came voluntarily for blood donation at blood bank, were found to have elevated blood sugar level ≥ 200 mg/dl, which is in accordance with the study done by J. Ramasamy *et al.*, 2016 who reported 15.05% subjects were diagnosed with diabetes among the blood donors [Figure 1].^[8]

Out of 54 subjects, 48 subjects were detected with diabetes. The prevalence of diabetes was found to be 3.97%. The findings is in accordance with the findings of Samad N. A. *et al.*, 2015, which reported the prevalence of undiagnosed diabetes 5% among the screened blood donors.^[9]

Qiao Q *et al.* from the Decoda study group reported that Indians have the highest prevalence of diabetes among Asian countries. The age at which the peak prevalence of diabetes was reached was ~ 10 years younger in Indian compared with Chinese and Japanese subjects.^[10] In our study 7.4% of all subjects who were detected diabetics were in the age group of 25–34 years. Our study thus supports the screening strategies to be directed towards younger age groups particularly in Indian (Asian) population [Table 4].

The correlation established between HbA1c and UCAR is in accordance with the findings of Haque N. *et al.*^[11], who evaluated the association of the aforesaid two variables from a cross sectional study and concluded that raised UACR is associated with HbA1c, and thus UACR should be estimated in monitoring the risk assessment of Type-2 DM in the patients with raised HbA1c.

Screening for diabetes is a resource intensive strategy particularly in underdeveloped and developing countries. Screening camps are organized to detect the burden of disease but may not prove fruitful as they cater to a small section of population. Voluntary blood donation screens can be resource minimal strategy to detect the community burden of diabetes and diabetic nephropathy as well as stimulus for initiating therapeutic modalities in patients detected to have diabetes and diabetic nephropathy.

Conclusion

In the present study capillary blood sugar test and OGTT test were implemented for the estimation of blood sugar level, which provides a relatively accurate tool for the purpose as compared to HbA1c for the Indian population. Greater expense incurred on HbA1C along with inter lab variability due to difference in test protocols supports the capillary blood glucose coupled with OGTT as a reliable screening method.

The findings indicate the prevalence of undiagnosed diabetes in central India region to be 4.47%, though this number is relatively

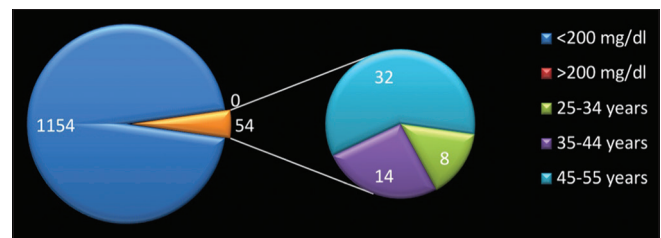


Figure 1: Results of random capillary glucose screening

Table 4: HbA1C (mean), eGFR values in sifferent subjects

No. of subjects	HbA1C (range)	HbA1C (mean)	UACR (mean)	eGFR (mean)	No of subjects microalbuminuria (UACR 30 - 300 mg/gm)	No. of subjects with overt proteinuria UACR > 300 mg/gm
22	7.4 - 8.6	8.05	48.66	95.38	3(13.63%)	Nil
20	8.7 - 11.8	9.63	115.3	96.34	5(25%)	1(5%)
06	11.8 - 14.2	13.0	215.06	97.88	3(50%)	1(16.66%)

lower to prevalence of undiagnosed diabetes detected by other population studies in the country ~10.1%, however this study also demonstrated that 31.24% (13 out of 48) diabetics had evidence of diabetic nephropathy. Thus, screening voluntary blood donors for diabetes can be implemented to diagnose undetected burden of diabetic nephropathy in population.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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