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Original Research Article

Establishment of Reference Interval of Blood Glucose and HbA1c in Tertiary Care Hospital of Anand District

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Abstract

Background: Health of an individual is conceptually different in different countries, in the same country at different times and in same individuals at different ages. The reference range varies considerably from one laboratory to another and is decedent on the population diet. Methodology, selection of reference group needs of the clinical. The clinical laboratory standard institute (CLSI, formerly known as NCCLS) recommended nonparametric (IFCC) recommends both nonparametric method and parametric method for the determination of reference ranges.

Material and Methods: Present study was carried out in Central diagnostic laboratory of tertiary care hospital of Anand district over the period of one year. This cross-sectional study includes total 500 blood reports of RBS, FBS, PP2BS and HbA1c of all the individual who attended the routine health Checkup, outpatient department attending the hospital. All the data were expressed a Mean±2SD. Data analysis was done by using Statistical Software (SPSS-17). Kolmogorov-Smirnov (Z-test) was applied for all the parameters.

Results and Discussion: Mean and SD values of random blood glucose, fasting blood glucose, postprandial blood glucose and HbA1c for male are 112.80±23.65 mg/dL, 99.02±9.99 mg/dL, 106.09±18.82 mg/dL, 5.59±0.38% respectively, and for female are 109.74±36.06 mg/dL, 100.51±10 mg/dL, 104.77±13 mg/dL, 5.65±0.38% respectively.

Conclusion: Hence, from this study we conclude that the reference range obtained for biochemical parameters of glucose observed in defined population in a city is different from the values provided by the diagnostic kits. But we found the reference range of HbA1c is similar to available reference range.

Keywords: Random Blood Glucose, Fasting Blood glucose and HbA1c.

Introduction

Health of an individual is conceptually different in different countries, in the same country at different times and in same individuals at different ages. It is thus a relative and not an absolute state. This means that the condition of individuals must be related to or compared with reference data. On comparing the individual's data collected during the medical interview, clinical examination,

and supplementary investigations with the reference data, the condition of individuals can be interpreted. A patient's laboratory result simply is not medically useful if appropriate data for comparison are lacking[1]. The reference range varies considerably from one laboratory to another and is decedent on the population diet. Methodology, selection of reference group needs of the clinical[2].

A reference value may then be defined as follows: a value obtained by observation or measurement of a particular type of quantity on reference individuals. The IFCC also defines other terms related to the concept of reference values reference population, reference sample group, reference distribution, reference limits, and reference intervals[3].

A patient's laboratory results simply are not medically useful if appropriate data for comparison are lacking. Medicine is an art and a science in the service of follow human beings. Physicians collect empirical data to improve the patients and interpret these data using scientific knowledge and professional experience. The reference range varies considerably from one laboratory to another and is dependent on the population diet. For the determination of reference range, the most important stage is the selection of the reference group and the standardization of per analytical factor[5,6]. The clinical laboratory standard institute (CLSI, formerly known as NCCLS) recommended non parametric (IFCC) recommends both non parametric method and parametric method for the determination of reference ranges[4,6].

Diabetes mellitus and coronary artery disease are major cause of morbidity and mortality in our country. The concept of reference values for routine monitoring of blood glucose in diabetes mellitus and HbA1c in patients at risk of coronary artery disease are of great significance in a selected population. Present study aimed to establishment of reference intervals of blood glucose [Random blood glucose (RBS), fasting blood glucose(FBS), Postprandial blood glucose(PP2BS)], HbA1c in healthy individuals who are coming for routine health check –up in tertiary care hospital of Anand district.

Material and Methods:

Present study was carried out in Central diagnostic laboratory of tertiary care hospital of Anand district over the period of one year. This cross-sectional study includes total 500 blood reports of RBS, FBS, PP2BS and HbA1c of all the individual who attended the routine health Checkup, outpatient department attending the hospital. The healthy individuals were selected on the basis of normal physical examination with no medical illness and the data was collected from LIS of Hospital.

Inclusion criteria: all healthy individual above 18 years of age attending the routine health checkup and OPD at Hospital.

Exclusion criteria: Patients with history of Diabetes mellitus, anemia, Cushing syndrome.

Statistical Evaluation:

In the nonparametric method the percentiles are simply determined by cutting off the required percentage of values in each tail of the subset reference distribution. Using the reference distribution, the reference interval can be computed. All the data were expressed a Mean±2SD. Data analysis was done by using Statistical Software (SPSS-17). Kolmogorov-Smirnov (Z-test) was applied for all the parameters. The reference limits are defined as the central 95% of the population Comprised between quantiles 2.5 and 97.5, leaving aside 2.5% of the individuals on both sides of the distribution. The transformation method recommended by the IFCC is based on multi-stage transformations, guided by the coefficients of skewness and kurtosis.

Procedure for estimation of reference limits:

1. Collection of reference values according to the recommended procedures.
2. **Inspection of the distribution of values:** This is done by displaying the values graphically in a histogram. The histogram is visually inspected for the presence of any skewness, kurtosis, outliers, and bi/poly modality. Visual inspection is a safeguard against the misapplication of statistical methods or the misinterpretation of their outcome.
3. **Inspection for any aberrant values and outliers:** An aberrant value is traced back to a gross deviation from the prescribed procedure for production of reference values. Some values may be detected as outliers, that is, values that stand unexpectedly far from most of the other reference values. Visual inspection of a histogram is a reliable method for identification of possible outliers.
4. **Parametric method of estimation of fractiles:** Statistical tests of goodness of fit of the distribution of the reference values to a Gaussian distribution are applied. When the data fit the Gaussian distribution, fractiles are estimated directly. If they do not fit Gaussian distribution, transformation of data is tried.

Results and Discussion:

The Study population was categorized into age group in years (18-30, 31-40-41-50, 51-60, 61-70, 71-80, >80) and gender as following Table 1,2,3,4.

According to our study (Table 5,6,7,8), Mean and SD values of random blood glucose, fasting blood glucose, postprandial blood glucose and HbA1c for male are 112.80±23.65 mg/dL, 99.02±9.99 mg/dL, 106.09±18.82 mg/dL, 5.59±0.38% respectively, and for female are 109.74±36.06 mg/dL, 100.51±10 mg/dL, 104.77±13 mg/dL, 5.65±0.38% respectively. In this study we tried to set up blood glucose and HbA1c individuals for normal healthy population of Anand district in Gujarat. We compared it with laboratory normal reference range used in our lab random blood glucose <200(mg/dl), fasting blood glucose <100(mg/dl), post-prandial blood glucose <140(mg/dl), HbA1c<5.7(%) when this normal range was compared with our reference intervals.

Published literature has confirmed that many of the reference values obtained from the developed countries differ significantly from what pertains in most African localities; thus, making it necessary to establish locally relevant values. The Clinical and Laboratory Standards Institute (CLSI) and the International Federation for Clinical Chemistry (IFCC) recommend that each laboratory establishes its own reference values[7]. Following the example of clinical chemists in Scandinavia, authors from many countries have recently adopted the terms reference values" and "reference intervals", and this new nomenclature is rapidly becoming the preferred clinical usage in North America, as well as in Europe[8]. A rational approach to providing a sound basis for interpretation of observed values calls for a theory, which describes the principles and procedures for selection of reference populations and definitions of reference values[9,10]. He reference intervals establish for the several labs serving a homogeneous population thought a geographic area is gaining acceptance[11].

Conclusion:

It is necessary to define specific reference intervals for Indian population because for our countries enormous ethnic and racial diversity. In this study, references ranges were developed for the following Parameters: RBS, FBS, PP2BS, HbA1c.

The values obtained from the study showed deviation from the values provided by the diagnostic kit inserts or literature. The results obtained from this study for biochemical parameters of Glucose and Hba1c are significant after detailed analysis for the defined population. As a uniform dietary pattern was not followed in this study, values might show variations. This study did not include any partition because of small sample size and needs to be revised with larger sample size.

Hence, from this study we conclude that the reference range obtained for biochemical parameters of glucose observed in defined population in a city is different from the values provided by the diagnostic kits. But we found the reference range of HbA1c is similar to available reference range. Hence establishing reference range for biochemical parameters in a selected population in more partitioned groups with larger sample size will be of great significance to the clinicians in making the decisions.

Table 1: Age and Sex wise distribution for Random Blood Glucose.

AGE	MALE	FEMALE	TOTAL
18-30	29	26	55
31-40	37	36	73
41-50	36	70	106
51-60	52	61	113
61-70	46	46	92
71-80	25	24	49
>80	10	2	12

Table 2: Age and Sex wise distribution for Fasting Blood Glucose

AGE	MALE	FEMAEL	TOTAL
18-30	78	47	86
31-40	27	18	45
41-50	41	68	109
51-60	58	70	129
61-70	34	44	79
71-80	18	27	46
>80	5	4	9

Table 3: Age and Sex wise distribution for Post prandial Blood Glucose

AGE	MALE	FEMALE	TOTAL
18-30	114	92	206
31-40	26	47	73
41-50	22	60	82
51-60	20	43	63
61-70	21	23	44
71-80	11	20	31
>80	1	4	5

Table 4: Age and Sex wise distribution for HbA1c.

AGE	MALE	FEMALE	TOTAL
18-30	55	29	84
31-40	26	35	61
41-50	44	51	97
51-60	44	53	98
61-70	50	51	102
71-80	19	28	47
>80	5	6	11

Table 5: Mean, SD for Reference range of Random Blood Glucose

NO	AGE	GENDER	MAEN (mg/dL)	STANDERD DAVIATION	RAFERANCE INTERVALES
1	18-30	M	112.06	18.17	93.89 -130.23
		F	111.21	6.754	104.45-117.96
2	31-40	M	111.76	23.65	88.104 -135.42
		F	111.14	23.64	87.50-134.78
3	41-50	M	111.37	23.61	87.76-134.98
		F	111.45	23.63	87.82-135.08
4	51-60	M	111.40	23.72	87.68-135.12
		F	111.37	23.67	87.7-135.04
5	61-70	M	111.57	23.48	88.09-135.05
		F	111.65	23.73	87.92-135.38
6	71-80	M	112.02	23.40	88.62-135.42
		F	112.02	17.94	94.35 -130.23
7	>80	M	112.46	23.70	88.76-136.16
8	TOTAL	M	112.80	23.6577	112.80-136.45
		F	109.74	36.06	73.68-145.85

Table 6: Mean, SD for Reference range of Fasting Blood Glucose.

NO.	AGE	GENDER	MAEN (mg/dL)	SATANDERD DAVIATION	RAFERANCE INTERVALS
1	18-30	F	99.80	9.961	89.84-109.76
		M	100.05	9.97	90.08-110-02
2	31-40	F	99.64	10.01	89.62-109.65
		M	99.85	1.41	98.70-100.99
3	41-50	F	100.03	9.99	90.04-110.02
		M	99.99	9.96	9.00.03-109.95
4	51-60	F	99.85	9.52	90.53-109.37
		M	99.90	1.52	98.38-101.42
5	61-70	F	99.85	9.90	89.95-109.75
		M	99.97	2.64	97.33-102.61
6	71-80	F	99.91	9.99	89.92-109.99
		M	99.82	2.11	97.66-101.97
7	>80	F	99..91	9.99	89.92-109.90
		M	100.02	10.12	89.99-110.14
8	TOTAL	F	99.02	9.99	89.03-109.01
		M	100.51	10.00	90.51-110.51

Table 7: Mean, SD for Reference range of Post Prandial Blood Glucose.

NO	AGE	GENDER	MAEN (mg/dL)	STANDERD DAVIATION	REFRANCE INTREVALES
1	18-30	F	102.11	19.02	83.09-121.13
		M	96.58	14.97	81.61-111.55
2	31-40	F	106.20	13.57	92.63-119.77
		M	103.70	18.86	84.864-122.56
3	41-50	F	111.72	10.97	100.75-122.69
		M	104.65	17.72	87.43-121.87
4	51-60	F	107	10.71	96.29-117.71
		M	113.53	13.00	100.53-126-53
5	61-70	F	110.73	15.19	95.54-125.92
		M	115.04	17.26	97.78-132.3
6	71-80	F	127.37	14.81	112.56-142.18
		M	113.85	11.22	102.63-125.07
7	>80	M	108.84	17.67	91.17-126.51
8	TOTAL	F	106.09	18.82	87.27-124.91
		M	104.77	13.00	91.77-117.77

Table 8: Mean, SD for Reference range of HbA1c.

NO	AGE	GENDER	MAEN (%)	STANDERD DAVAVIATION	RAFERANCE INTERVALES (%)
1	18-30	F	5.49	0.32	5.22-5.81
		M	5.50	0.28	5.22-5.78
2	31-40	F	5.42	0.28	5.14-5.7
		M	5.52	0.27	5.25-5.79
3	41-50	F	5.65	0.38	5.27-6.02
		M	5.61	0.38	5.23-5.99
4	51-60	F	5.63	0.38	5.25-6.01
		M	5.74	0.42	5.32-6.16
5	61-70	F	5.65	0.32	5.33-5.97
		M	5.72	0.86	5.44-6
6	71-80	F	5.66	0.28	5.38-5.94
		M	5.72	0.25	5.46-5.97
7	>80	F	5.8	0.25	5.54-6.05
		M	5.8	0.25	5.54-6.055
8	TOTAL	F	5.59	0.38	5.52-6.28
		M	5.65	0.38	5.27-6.03

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