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Original Article

IDENTIFICATION AND ASSESSMENT OF PREDIABETES-A RURAL INDIAN STUDY (A CORRELATIVE STUDY BETWEEN QUESTIONNAIRE AND BIOCHEMICAL ANALYSIS)

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ABSTRACT

Objective: To identify and prevent the vulnerable prediabetic population becoming diabetic patients in the future using the Indian Diabetic Risk Score (IDRS) and to evaluate the performance of the IDRS questionnaire for detecting prediabetes and predicting the risk of Type 2 Diabetes Mellitus in Chidambaram rural Indian population.

Methods: A cross-sectional descriptive study was carried out among patients attending a master health check-up of RMMCH hospital located at Chidambaram. The IDRS was calculated by using four simple measures of age, family history of diabetes, physical activity, and waist measurement. The relevant blood test, like Fasting plasma glucose (FBS), Glycated hemoglobin (HbA1C) test, were observed for identifying prediabetes. Subjects were classified as Normoglycemic, prediabetics, and diabetics based on the questionnaire and diagnostic criteria of the Indian Council of Medical Research (ICMR) guidelines.

Results: In the study, sensitivity and specificity of IDRS score were found to be 84.21% and 63.4% respectively for detecting prediabetes in community with the positive predictive value of 51.6% and negative predictive value of 89.6% and prevalence of prediabetes in the Chidambaram rural population is 31.6% among the 60 participants.

Conclusion: The Indian diabetic risk score questionnaire designed by Madras diabetic research federation is a useful screening tool to identify unknown type 2 diabetes mellitus. The questionnaire is a reliable, valuable, and easy to use screening tool which can be used in a primary care setup.

Keywords: IDRS, Prediabetes, FBS, HbA1C, Sensitivity, Specificity, Positive predictive value, Negative predictive value

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INTRODUCTION

Diabetes is one of the leading non-communicable diseases affecting a larger proportion of the population in the world. The global prevalence of type 2 diabetes mellitus in the year 2000 among adults was estimated to be 171 million and will rise to 366 million by 2030 and India is regarded as the diabetic capital of the world with an estimate of 72.9 million diabetic patients [1, 2]. Hence the identification of persons with the probability of developing diabetes becomes crucial. In this regard, prediabetes as an entity becomes an important factor in identifying high-risk individuals and will go a long way in the prevention and delay of the development of Type 2 diabetes mellitus. The term "Prediabetes" refers to a situation where the blood glucose levels are higher than normal, but not high enough to warrant a diagnosis of diabetes [3]. In this regard, according to the Indian diabetes study report of The Indian Council of Medical Research (ICMR), the vulnerable prediabetic population is estimated to be around 77.2 million currently. Which is more than the current diabetic population in India [4].

Hence, the Prediabetic population has a potential risk of transforming itself into overt diabetes in 5 y, if not identified, and interviewed with necessary lifestyle modifications at once [5]. This investigation was embraced to analyse patients in the prediabetic stage and their bunching with the other risk factors for diabetic mellitus. The clustering of risk factors such as overweight and obesity, being older than 40 y, sedentary habits, smoking, alcoholism, hypertension, and intake of fruits and vegetables were studied [6]. Early diagnosis and intervention of prediabetic patients and their cluster of risk factor can prevent the cardiovascular events and complications of diabetes such as diabetic retinopathy, neuropathy, and nephropathy [7].

Prediabetics can be identified with several assessment questionnaires; the most common is the IDRS, ADA Questionnaire, CANRISK Questionnaire, AUDRISK Questionnaire, FINRISK Questionnaire [8]. Hence, we aim to identify the vulnerable prediabetic population by way of assessment through the standard Indian Diabetes Risk Score (IDRS). This can be used in identifying pre-diabetic population and prediabetes would be confirmed and verified biochemically (after obtaining informed consent) [9]. Mandatory biochemical protocol as per ICMR guidelines recommendation will be followed, namely, FPG of 110-125 mg/dl (5.6-6.9 mmol/l), HbA1C of 5.7-6.4 % (39-46 mmol/l) [10]. The main objective of the study was to assess the performance of the Indian Diabetic Risk Score (IDRS) questionnaire for detecting and predicting risk of type-2 Diabetes Mellitus in a rural Indian population and to identify, assess and prevent the vulnerable prediabetic population becoming diabetic patients in future. We expect considerable outcome for proper prediabetic risk assessment questionnaire for rural Indian set up and also this study group will propose tailor-made lifestyle modification for the identified prediabetics in this study.

MATERIALS AND METHODS

The study was approved by the Institutional Human Ethics Committee of Annamalai University (Approval No. IHEC/0390/2018) and the date of the approval is 09.01.2019. A cross-sectional descriptive study was carried out among patients attending a master health check-up of RMMCH hospital, Annamalai University located at Chidambaram. The study method involves the selection of participants based on inclusion criteria (non-diabetic patients, subject of both genders and age group between 17 to 60 y, participants willing to give consent form and to participate in the study were included) and exclusion criteria (patients who were not willing to participate, known history of DM, pregnant and lactating women). The consent form was obtained from participants who were willing to participate in the study.

Data was recorded on the "Prediabetes risk assessment Questionnaire" and information regarding age, socioeconomic

status, family history of diabetes and hypertension, physical activity, dietary pattern, weight, height, BMI, waist circumference, and history of smoking and alcohol consumption were recorded. Standard methods were used to measure weight and height and BMI was calculated.

The IDRS was calculated using age, family history of diabetes, physical activity, and waist measurement. Participants were

categorized into low (<30), medium (30-59), and high (>60) risk groups based on the IDRS questionnaire. Participants with prediabetes risk were identified by a questionnaire and confirmed with the biochemical investigation. The relevant blood test was taken for identifying prediabetic using Fasting plasma glucose (FBS), Glycated haemoglobin (HbA1C) test. Subjects were classified as normal or prediabetics based on the questionnaire and diagnostic criteria of the Indian Council of Medical Research (ICMR) guidelines.

Table 1: ICMR diagnosis criteria for diab	etes and prediabetes [10]
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Parameters	Normoglycemic	Prediabetes	Diabetes
FBS	<110 mg/dl	110-125 mg/dl	>126 mg/dl
2-hrs OGTT	<140 mg/dl	140-199 mg/dl	>200 mg/dl
HbA1c	<5.7%	5.7-6.4%	>6.5%

The collected information was tabulated, processed and analysed using IBM SPSS statistical tool.

Measures of diagnostic accuracy: sensitivity, specificity, PPV, and NPV

The basic measures of quantification of the diagnostic accuracy of a test include sensitivity and specificity, positive predictive value, and negative predictive value and were calculated using the following equations. The criteria used for assessing True positive, true negative, false positive and False-negative are discussed in foot note of table 6, IDRS VS HBA1C cross-tabulation

Sensitivity =
$$\frac{\text{True Positive}}{\text{True Positive} + \text{False Negative}} \times 100$$

The sensitivity of a diagnostic test quantifies its ability to correctly identify subjects with the disease condition. It is the proportion of true positives that are correctly identified by the test.

Specificity =
$$\frac{\text{True Negative}}{\text{True Negative} + \text{False positive}} \times 100$$

The specificity is the ability of a test to correctly identify subjects without the condition. It is the proportion of true negatives that are correctly identified by the test

Positive Predictive Value =
$$\frac{\text{True Positive}}{\text{True Positive} + \text{False Positive}} \times 100$$

Positive predictive value shows the probability of a person with a disease or condition when the test is positive.

egative Predictive Value =
$$\frac{\text{True Negative}}{\text{True Negative} + \text{False Negative}} \times 100$$

Negative predictive value shows the probability of a person with not developing disease or condition when the test is negative [11-13].

RESULTS

Ne

A total of 60 participants were enrolled in the study. The subjects were divided into three age groups, viz,<35; 35 to 49;>50 y.

Table 2: Age-wise distribution of study participants (N=60)

Age	No of participants (N=60)	Percentage (%)
<35	18	30%
35-49	19	31%
>50	23	38%
Total	60	100%

The age wise-distribution of the study had shown that the maximum number of participants (23 participants, 38%) belongs to the age group of>50 y, among the total of 60 participants. However, there was a gradual increase in the enrolment of patients as the age increases, but the change is not significant.

Table 3: Distribution of subj	ects in categories of BM	l classification (N=60)

BMI (kg/m ²)	No of participants (N= 60)	Percentage
Underweight (<19)	2	3%
Normal (20-24.9)	14	23%
Overweight (25-29.9)	25	41%
Obese (>30)	19	31%
Total	60	100%

The subjects were classified in to different categories of BMI, based on the revised consensus guidelines for Asian Indians. In the study population, 41% were considered overweight, 31% were considered obese, 3% were considered underweight, and 23% were having normal BMI. Since BMI is one of the predisposing factor for the development of diabetes, around (41+31=72%) of patients have a risk to develop diabetes in the future.

In the present study out of 60 subjects, 31(52%) come under high risk, 22 (37%) come under moderate risk, 7 (11.6%) come under low risk as per the IDRS risk score. The study shows that the majority (52%) of subjects come under high-risk category and this is

an alarming signal as this 52% of patients have a greater probability to develop diabetes within a span of 5 to 10 y.

The values of FBS and HbA1c were comparable in case of prediabetic category (33%, 32%), whereas in case of hyperglycaemic, FBS and HbA1C were showing lower percentages (0, 3.3%) diabetes.

According to biochemical investigations (FBS and HbA1C), percentages of participants having a prediabetic risk factor were 33% and 32% respectively and were comparable. However, according to IDRS Score, 52% of patients belong to the high-risk category; this provides a strong signal that they may develop

diabetes in the future. IDRS score comprises various parameters like waist circumference (physiology), physical activity (lifestyle), and family

history (genetic predisposition) and it is a more relevant measure and to predict the probability of developing diabetes in the future.



Fig. 1: Comparison of normoglycemic, prediabetic and diabetic population-based on FBS and HbA1c result

Table 4: Distribution of study subjects according to demography details and risk as per IDRS (N=60)

Variables		IDRS Risk						Total	
		Low		Moderate	9	High			
		No	%	No	%	No	%	No.	%
Gender	Male	7	11.6%	14	23.3%	17	28.3%	38	63.3%
	Female	0	0%	9	15%	13	21.6%	22	36.6%
Age	<35	6	10%	9	15%	1	1.6%	16	26.6%
	35-45	1	1.6%	9	15%	10	16.6%	20	33.3%
	>50	0	0%	5	8.3%	19	31.6%	24	40%
Food Habits	Vegetarian	2	3.3%	1	1.7%	4	6.7%	7	11.6%
	Non-Vegetarian	5	8.3%	22	36.7%	26	43.3%	53	88.3%
Alcoholic	Yes	2	3.3%	9	15%	8	13.3%	19	31.6%
	No	5	8.3%	14	23.3%	22	36.7%	41	68.4%

Among 38 male participants, $(17/38 \times 100=44.7\%)$ were in IDR high-risk category whereas among 22 female participants, $(13/22\times100=59.1\%)$ were in IDRS high-risk category. The reason for the higher % in females may be due to lesser physical activity, hormonal imbalances, and sedentary lifestyle.

Among 24 participants in the age group of (>50 y), 19 participants (19/24x100= 79.1%) were having a high-risk IDRS score.

Regarding food habit, among 7 vegetarians, 4 participants (4/7x100=57.1%) of participants belong to high-risk IDR score high-risk, and among 53 non-vegetarians, 26 participants (26/53 x100= 49%) of participants belong to high-risk IDR score.

On analysing the association between alcoholic and IDRS in our study, among 19 alcoholics, 8 participants (8/19x100=42.1%) belong to high-risk IDR score and among 41 non-alcoholics, 22 participants (22/41x100=53.6%) belongs to high-risk IDR score. Since we are measuring parameters mostly from healthy people, the majority of participants were occasional drinkers.

Body Mass Index (BMI) is considered to be one of the contributing risk factors for prediabetes. Among 25 participants in BMI overweight category, 13 participants (13/25x100=52%) belong to the high-risk category, and among 15 participants in BMI obese category, 11 participants (11/15x100=73.3%) belong to high-risk category. Hence as BMI increases, the chance of getting prediabetes also increases.

Table 5: Distribution of stud	v subjects according to	BMI details and risk as i	per IDRS
	, ,		

BMI * II	ORS cross-tabulation								
Count									
Categories IDRS								Total	
		Low ris	k	Moderate	e risk	High ris	k		
	Below Weight	2	50%	2	50%	0	0%	4	
BMI	Normal Weight	3	18.7%	7	43.7%	6	37.1%	16	
	Over Weight	1	4%	11	44%	13	52%	25	
	Obese	1	6.6%	3	20%	11	73.3%	15	
Total		7	11.6%	23	38.3%	30	5S0%	60	

Table 6: IDRS VS HBA1C cross-tabulation

IDRS VS HBA1C cross-tabulation						
Count		HBA1C		Total		
		Positive	Negative			
IDRS	Positive	16	15	31		
	Negative	3	26	29		
Total		19	41	60		

True positive 🗖, False negative 🗖, False positive 🗖, True negative 🗖

> True Positive value indicates no. of participants who were positive both in the IDRS score (having scores more than 60) and HbA1C values (having HbA1C value between 5.7 to 6.4%). In our study, true positive value equals 16

➤ True negative value indicates no. of participants who were negative both in the IDRS score (having scores less than 60) and HbA1C values (having HbA1C value less than 5.7 as well as \geq 6.5%). In our study, true negative value equals 26.

➤ False-negative value indicates no. of participants who were negative in IDRS score (having scores less than 60) and positive in the HbA1C values (having HbA1C value between 5.7 to 6.4%). In our study, false-negative value equals 3.

➤ False Positive value indicates no. of participants who were positive in IDRS score (having scores more than 60) and negative in the HbA1C values (having HbA1C value less than 5.7 as well as \geq 6.5%). In our study, false-negative value equals 15.

Therefore:

1. Prevalence =
$$\frac{\text{True Positive + False Negative}}{\text{Total Population}} \times 100$$
$$= (16 + 3)/60 \times 100$$

Prevalence = 31.6%

2. Sensitivity =
$$\frac{\text{True Positive}}{\text{True Positive} + \text{False Negative}} \times 100$$
$$= \frac{16}{(16+3)} \times 100$$

Sensitivity = 84.21%

3. Specificity =
$$\frac{\text{True Negative}}{\text{True Negative} + \text{False positive}} \times 100$$
$$= 26/(26 + 15) \times 100$$

Specificity = 63.4%

5.

4. Positive Predictive Value =
$$\frac{\text{True Positive}}{\text{True Positive} + \text{False Positive}} \times 100$$
$$= \frac{16}{(16+15) \times 100}$$

Positive predictive value = 51.6%

Negative Predictive Value

$$= \frac{\text{True Negative}}{\text{True Negative} + \text{False Negative}} \times 100$$

$$= 26/(26+3) \times 100$$

Negative predictive value = 89.6%

Based on the calculations, the prevalence for prediabetes was around 31.6% among 60 participants drawn from the rural population. The sensitivity and specificity of the IDRS score were found to be 84.21% and 63.4%, respectively. Positive predictive values were found to be 51.6% and negative predictive values were found to be 89.6%. Positive predictive value 51.6% shows that the probability of a person with prediabetes when the IDRS score is positive (having scores more than 60). Negative predictive value 89.6% shows the probability of a person not developing prediabetes when the IDRS score is negative (having score is negative (having score less than 60).

In our study, the sensitivity of 84.21%, a specificity of 63.4% was observed for determining undiagnosed diabetes in the community with a positive predictive value of 51.6% and a negative predictive value of 89.6%.

DISCUSSION

There are many Diabetic risk assessment questionnaires and tools developed by various National and International diabetic associations all over the world, and they have variations in assessment based on the ethnic group, lifestyle, and races. The most commonly used Questionnaires are ADA Questionnaire, CANRISK Questionnaire, AUDRISK Questionnaire, and Indian Diabetic Risk Score (IDRS), IDRS developed by Chennai Urban Rural Epidemiology Study (CURES) and Madras Diabetic Research Foundation (MDRF) is found to be the most suitable, simple, and easy tool to identify undiagnosed diabetes in our country [9]. The IDRS is calculated using four risk factors: age, family history of diabetes, physical activity, and waist circumference measurement. This is of great significance as the use of such a scoring system could prove to be a cost-effective tool for screening of diabetes. Further, the use of such a risk score would be of great help in developing countries like India where there is a marked explosion of diabetes, and over half of the cases remain undiagnosed diabetes [14]. Measurement of waist circumference as a measure of abdominal obesity plays a significant role in the identification of the development of type 2 diabetes mellitus. In the Indian population lean body mass index also is considered as one of the factors for the development of Type 2 diabetes mellitus. Hence, instead of BMI, the measurement of waist circumference makes a better screening tool for assessing type 2 diabetes mellitus and its risk in the Indian population [15, 16].

From the results of our study using Indian diabetic risk score, a higher degree of sensitivity 84.21% and specificity of 63.4% were observed for determining undiagnosed diabetes in the community with a positive predictive value of 51.6% and negative predictive value of 89.6%. This value is comparable with the value of IDRS developed by Mohan et al. (2005). CURES study has revealed sensitivity (72.5%) and specificity (60.1%) for determining undiagnosed diabetes in the community with a positive predictive value of 17.0%, the negative predictive value of 95.1% when the IDRS Score>60 [17]. Similarly, Stanley et al. validate IDRS in the South Indian population, and study results show sensitivity and specificity of 100% and 17%. Puja Dudeja et al. has used IDRS and predicted the risk of diabetes with a sensitivity of 95.12% and 28.95% when the sore>60 [18, 19]. Ramachandran et al. also developed a Diabetes Risk Assessment Score for the south India population, which was validated in three cohorts. They have included BMI also for the assessment of the risk of type 2 diabetic Mellitus with a score of>21 gave a sensitivity, specificity, positive predictive value, and negative predictive value of 76.6%, 59.9%, 9.4%, and 97.9% [20]. The prevalence of prediabetes in the current study was 31.6%. The higher prevalence of prediabetic in a rural Tamil Nadu population may be due to a lack of awareness about a healthy diet and lack of physical activity. Beagley *et al.* in the global estimation study reported a prevalence of prediabetic and diabetes in adults to vary between 24.1% and 75.1% respectively [21]. Dasappa *et al.* had reported a prevalence of diabetic and prediabetic in the urban slum of Bangalore as 12.33% and 11.57% respectively [22]. Ravikumar et al. has carried out a study in the urban locality of Chandigarh and reported a low prevalence (6.3%) of prediabetics. Thus prediabetic population has a potential risk of transforming itself into overt diabetes in 5 y, if not identified and interviewed with necessary lifestyle modification at once [23]. The current study shows that diabetes is one of the major risk factors for developing cardiovascular events and death [24]. Therefore, early diagnosis and intervention of prediabetics and their cluster of a risk factor can prevent the cardiovascular events and complications of diabetes such as diabetic retinopathy, neuropathy, and nephropathy.

In developing countries like India, half of the newly diagnosed patients were identified only at a later stage due to a lack of awareness and knowledge about diabetes. IDRS is user friendly, simple, fast, economical, and effective screening tool to identify prediabetes at an earlier stage, prior to the actual confirmation of diabetes using blood level investigation. This will help to reduce the screening cost of diabetes by nearly half. IDRS also help to identify a person at risk of having prediabetes in our population. Moreover, IDRS will help to create awareness and motivate people, who have a higher risk of developing diabetes in the future and to monitor blood glucose levels frequently as a precautionary measure to predict diabetes.

LIMITATION OF THE STUDY

Initially, 150 participants were enrolled in the study from the Department of medicine, RMMCH, Chidambaram. But some of them were not willing to take the HbA1c test as it involves invasive

procedures and is quite expensive. Since it is a self-funding project, we could not take the HbA1c test for a few participants.

CONCLUSION

In this study, we have assessed the performance of Indian diabetic risk score (IDRS) in a rural population setup of Chidambaram From the study we conclude that IDRS is found to be a simple, fast, non-invasive and fairly accurate tool for screening of undiagnosed Type 2 diabetes which can be used in a primary health care facility. According to our study, the prevalence of prediabetes in the rural population is 31.6% with a sensitivity of 84.21% and specificity of 63.4% when the IDRS score was more or equal to 60, with a positive predictive value of 51.6% and negative predictive value of 89.6%. Since India is considered as the diabetic capital of the world with an estimate of 70 million diabetic patients and still a higher estimate of around 77 million identified as prediabetes, our study can make a significant contribution in decreasing the burden of diabetes in the near future.

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AUTHORS CONTRIBUTIONS

All listed authors have contributed equally to the design and perform of the research to the analysis of the results and to the writing of the manuscript.

CONFLICT OF INTERESTS

The authors declare that there are no conflicts of interests.

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