ABSTRACT

The relevant blood test, like Fasting plasma glucose (FBS), Glycated hemoglobin (HbA1C) test, were observed for identifying prediabetes. Subjects keywords: 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.

The rural population is 31.6% among the 60 participants. The 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.

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 2020 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 by [7].

Prediabetes 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 pre-diabetes 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 diabetes and prediabetes [10]

| Parameters      | Normoglycemic | Prediabetes | Diabetes |
|-----------------|---------------|-------------|---------|
| FBS (mg/dl)     | <110          | 110-125     | >126    |
| 2-hrs OGTT      | <140          | 140-199     | >200    |
| 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

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

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.

\[
\text{Specificity} = \frac{\text{True Negative}}{\text{True Negative + False Positive}} \times 100
\]

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.

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

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

\[
\text{Negative Predictive Value} = \frac{\text{True Negative}}{\text{True Negative + False Negative}} \times 100
\]

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

### RESULTS

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 subjects in categories of BMI classification (N=60)

| BMI (kg/m²) | 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...
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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 to predict the probability of developing diabetes in the future.

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

| Variables      | IDRS Risk | Total |
|----------------|-----------|-------|
|                | Low   | Moderate  | High  | No | %   | No | %   | No | %   |
| Gender         |       |           |       |    |     |    |     |    |     |
| Male           | 7     | 11.6%     | 14    | 23.3% | 17 | 28.3% | 38 | 63.3% |
| Female         | 0     | 0%        | 9     | 15%  | 1   | 1.6%  | 16 | 26.6% |
| 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 x 100 = 44.7%) were in IDR high-risk category whereas among 22 female participants, (13/22x100= 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 study subjects according to BMI details and risk as per IDRS**

| BMI Categories | IDRS | Total |
|---------------|-----|-------|
|               | Low risk | Moderate risk | High risk | Total |
| Below Weight  |   2  | 50%   | 2  | 50% | 0   | 0%   | 4 |   |
| 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  | 55%  | 60 |   |

**Table 6: IDRS VS HBA1C cross-tabulation**

| Count | HBA1C | Total |
|-------|-------|-------|
|       | Positive | Negative | Total |
| IDR   | 16      | 15      | 31   |
| Negative | 3      | 26      | 29   |
| Total | 19      | 41      | 60   |

True positive [ ], False negative [ ], False positive [ ], True negative [ ]
Therefore:

- **Positive predictive 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 ≥ 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%).

- **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 ≥ 6.5%). In our study, false-negative value equals 3.

- **Positive both in the IDRS score (having scores more than 60) and negative both in the IDRS score (having scores less than 60).**

- **Negative both in the 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, true negative value equals 26.**

From the results of our study using Indian diabetic risk score, a higher degree of sensitivity 63.4% and specificity 89.6% was 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 score ≥ 60 [18, 19]. Ramachandran et al. also developed a Diabetes Risk Assessment Score for the south Indian 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 healthy habits 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]. Ravi Kumar et al. has carried out a study in the urban locality of Chandigarh and reported a low prevalence (63%) of prediabetics. Thus prediabetic population has a potential risk of transforming itself into overt diabetes in 5y. If not identified and intervened, it is 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 prediabetes 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, RMCH, Chidambaram. But some of them were not willing to take the HbA1c test as it involves invasive and time-taking.
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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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