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# Development and validation of a risk assessment tool for uncontrolled type 2 diabetes among patients in South Karnataka, India

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## ABSTRACT

**Introduction** Diabetes is a chronic medical condition with severe complications mainly caused due to unhealthy lifestyles in genetically susceptible individuals. This study attempts to develop a non-invasive risk assessment tool to identify patients with uncontrolled type 2 diabetes mellitus (T2DM) in southern India.

**Methodology** An exploratory study was conducted among 545 patients with T2DM in the Mysuru district, South India for 6 months. A prevalidated questionnaire was used to collect data. Univariate and multivariate logistic regression analysis was performed to develop the risk score. Receiver-operating characteristic (ROC) curve and area under the curve (AUC) were used to evaluate the cut-off for the risk score. The risk score is specifically designed for the population of South Karnataka, India.

**Results** Out of the 545 study participants, the prevalence of uncontrolled diabetes was 59.9%. Physical activity, duration of diabetes, diabetic diet, regular health check-ups, history of hypertension, smoking history and alcohol consumption were factors significantly associated with uncontrolled diabetes ($p<0.05$). For an optimum cut-off point of >13.50, the risk assessment model showed a moderate sensitivity of 71.3%, specificity of 61%, positive predictive value of 73.2% and negative predictive value of 58.3%. The ROC curve was plotted for the model with an AUC of 0.726 (95% CI 0.683 to 0.769).

**Conclusion** This study developed 'Diabetes Care', a simple web-based, non-invasive and inexpensive tool for identifying individuals at risk of developing uncontrolled T2DM in the future.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ India is referred to as the diabetic capital of the world.
⇒ More than half of the newly diagnosed diabetics are unaware of their condition until a complication manifests.

### WHAT THIS STUDY ADDS

⇒ A risk assessment tool was developed for uncontrolled type 2 diabetes.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Risk tools are simple and easy to use for early screening and to enhance the quality of life.
⇒ This study introduced 'Diabetes Care', a web-based tool for identifying individuals at risk of developing uncontrolled type 2 diabetes.

## INTRODUCTION

Diabetes mellitus (DM) is one of the serious persistent challenges confronting healthcare systems globally. By 2040, the International Diabetes Federation projects that 642 million people will have Diabetes.[1] Among 422 million people worldwide with diabetes, the majority live in low-income and middle-income countries (LMICs), and 1.5 million deaths are directly attributed to diabetes each year. Over the past few decades, there has been a consistent rise in both the incidence and prevalence of diabetes.[2] The projections for DM are worrying. T2DM, which accounts for 90% of all cases of diabetes, has spread throughout the world and is now a leading cause of disability and death in even younger age groups. Previously thought to be a disease of the 'wealthy' Western countries, T2DM now affects people of all ages in many developing nations, including China and India, which has reached epidemic levels.[3]

In addition, the proportion of adults aged 20–79 years with undiagnosed diabetes was estimated to be 90% of the diabetic population in LMICs compared with 33% in high-income countries. Diabetes is a global health concern that poses a threat to the economy of developing nations, especially India. India's large population and socioeconomic transitions have made it an epicentre of diabetes. Diabetes is more prevalent among Indians than other ethnic groups for several reasons,

including a lack of awareness of the disease and its complications, inadequate access to healthcare, high costs, non-adherence to treatment and a lack of accountability.[4]

According to studies, more than 60% of newly diagnosed diabetics are unaware of their condition until a complication manifests, and one-third of all diabetics go undiagnosed. Because of the way that the disease progresses, early detection is becoming more and more important.[5] It is well known that diabetes is a major risk factor for premature death. Long-term complications of diabetes are traditionally classified as microvascular or macrovascular. Macrovascular diabetes complications, such as coronary heart disease, stroke and peripheral vascular disease, as well as microvascular complications like end-stage renal disease, retinopathy and neuropathy, as well as lower-extremity amputations, account for a large portion of the diabetes burden.[6] Lifestyle changes and pharmacological treatment can prevent or delay complications of T2DM. Therefore, identifying people who are at risk of developing uncontrolled diabetes in the future is critical to reducing the diabetes burden and its complications.[7]

To lessen this impact, India needs an effective, non-invasive screening tool for DM such as the diabetes risk assessment tools, which are convenient and practical for early screening and detection of diabetes to prevent diabetes-related morbidity, lower the cost of healthcare and enhance the quality of life.[8] In recent years, multivariate risk scores have been developed to predict the risk of developing diabetes in healthy individuals. These risk scores are recommended in the most recent practice guidelines for preventing diabetes and are used in prevention programmes in some Western nations.[9]

Although many diabetic risk prediction models are available for use, a tool to predict risks for patients with uncontrolled T2DM is lacking. This study was proposed to develop and validate a non-invasive and self-administered risk assessment tool for patients with uncontrolled T2DM in southern India.

## OBJECTIVES

- To develop a non-invasive and self-administered risk assessment tool for patients with uncontrolled T2DM in southern Karnataka, India.
- To validate the risk assessment tool for uncontrolled diabetes among adults.

## MATERIAL AND METHODS

### Study design

An exploratory study was conducted among 545 patients with T2DM attending the outpatient department of a tertiary healthcare centre located in the Mysuru district, south Karnataka, India for a period of 6 months (January–July 2022). This study included all patients over the age of 18 years with T2DM who were being treated with insulin and/or oral hypoglycemic agents (OHA) and had consented to participate. Patients under the age of 18 years, those with severe complications, and pregnant women were all excluded from the study.

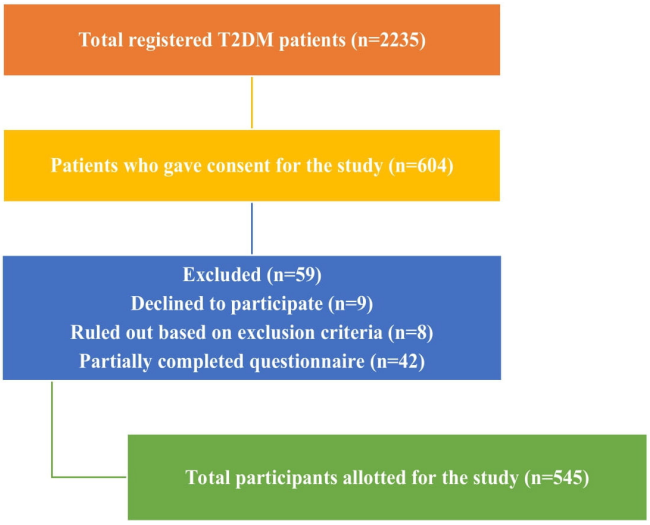


**Figure 1** Methodology flow chart. T2DM, type 2 diabetes mellitus.

### Sampling

A total of 2335 patients are registered with the diabetic clinic of JSS Hospital, Mysuru, India. This list includes patients residing in other states of Karnataka. All were invited to participate in the study and 604 responded positively. 59 participants did not match the inclusion criteria and were excluded from this study. Finally, a total of 545 participants were included in the analysis (figure 1).

### Research tool

A prevalidated questionnaire was used to collect the information from the participants. The questionnaire was divided into three sections.

Part 1 asked for sociodemographic information such as age, gender, religion, socioeconomic status (modified Kuppuswamy classification), education, occupation and income. Part 2 elicited information about their behavioural habits (alcohol consumption, smoking, exercise), diabetic history (symptoms, family history, complications, medications, diabetic diet and health check-ups) and other medical histories (hypertension and dyslipidaemia) and part 3 elicited anthropometric measurements (height, weight, waist circumference and hip circumference) and glycated hemoglobin (HbA1c) test value. To validate the questionnaire, a pilot study was conducted on 30 patients with diabetes, who were later removed from the study. The Cronbach's alpha score is 0.843. Thus, the questionnaire's validity and reliability were determined (online supplemental materials).

HbA1c was used to determine the glycaemic status of patients with T2DM. We classified the patients as having controlled diabetes (HbA1c<7) or uncontrolled diabetes (HbA1c≥7) based on their most recent HbA1c value.[10] Physical activity was classified based on both occupational and non-occupational-related activities. Adults were classified based on at least 150 min of moderate exercise per

week, which can be spread throughout the week.[11] Duration of diabetes was classified as <5 years, 5–10 years and more than 10 years.[12] A diabetic diet includes avoiding sweets, small frequent meals, healthy snack options (mid-morning and evening) and the plate method during the meal. If all of these instructions were followed daily, they were considered as those who followed a regular diabetic diet.[13] Regular health check-ups were classified based on whether consulted a doctor or did lab investigations (random blood sugar (RBS), fasting blood sugar (FBS), post-prandial blood sugar (PPBS), blood pressure (BP), HbA1c) at least once every 3 months.[14] Hypertension was defined as a BP>140/90 mm Hg or a self-reported diagnosis. Smoking and alcohol status were based on the patient's self-reported data.

### Study procedure

The participant's data were collected during their routine health check-up visits to the diabetic clinic. The purpose and procedure of the study were explained to the participants. The questionnaires were filled out by the research team through interpersonal interviews. The HbA1c tests were conducted for the patients at the visit, and the values were recorded in the questionnaire.

### Patient and public involvement

Data were collected from patients registered with the diabetic clinic of JSS Hospital, Mysuru over the age of 18 years with T2DM, treated with insulin and/or OHA drugs and had given consent to participate. Patients under the age of 18 years, those with severe complications, and pregnant women were all excluded from the study. The research questions were framed and a pilot study was conducted on 30 patients with diabetes to validate the questionnaire. These patients were excluded from the final analysis. Once the questionnaire's validity and reliability were established, it was shared with 545 patients with diabetes who were explained in detail the purpose and procedure of this study before getting their consent.

### Statistical analysis

The data collected were entered into a Microsoft Excel 2019 spreadsheet followed by analysis using SPSS Windows V.26 (IBM, Released 2019, IBM SPSS Statistics for Armonk).

The demographic characteristics such as age, gender, occupation are represented using the arithmetic mean, SD and percentages. The prevalence is represented in percentages. The possible associations between the selected demographic variables (age, gender and education) and diabetic status were found using the $\chi^2$ test/Fisher's exact test. A $p<0.05$ was considered statistically significant.

Univariate logistic regression was done to identify the significant risk factors for uncontrolled diabetes. The non-significant factors were eliminated.

Multivariate logistic regression analysis was performed to develop the scores for each significant variable. Odds ratio (OR) was calculated and the predictive variables were identified. The risk score was developed by multiplying the regression coefficient by 10 and rounding off to the nearest integer for each significant variable in the multiple logistic regression analysis. The total risk score for an individual patient was calculated by adding the score for each variable in the risk model.

The receiver-operating characteristic (ROC) curve and the area under the curve (AUC) were used to evaluate the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). The cut-off for the risk score was identified based on maximum sensitivity and specificity.

## RESULTS

Out of the 545 study participants, 308 (56.5%) were males and 237 (43.5%) were females. The mean age of the study participants was 55.61±12.185 years. The prevalence of uncontrolled diabetes in our study was 59.9%. 91% of the participants were married, and 1% of them were divorced. Most study participants had completed middle school (19.8%) and high school (19.4%). Hindus (492, 90.3%) make up the majority of participants, followed by Muslims (36, 6.6%) and Christians (17, 3.1%).

In the current study, 269 participants (49.4%) were exercising regularly, compared with 279 participants (50.6%) who were not. 88.1% of participants regularly took their medication while 11.9% did not. 73.2% of the participants saw a doctor or underwent lab tests (RBS, FBS, PPBS, BP and HbA1c) at least once every 3 months, compared with 146 (26.8%) who did not. 319 (58.5%) of the study participants had a history of hypertension while 238 (43.7%) had a history of dyslipidaemia. The majority of study participants (56.5%) did not maintain a healthy diet while 83 (15.2%) were smokers and 99 (18.2%) consumed alcohol.

Tables 1–3 show the sociodemographic, personnel, medical and anthropometric factors associated with uncontrolled diabetes.

Education of the participants, physical activity, duration of diabetes, type of medication, diabetic diet, regular health check-ups, history of hypertension and dyslipidaemia, smoking history and alcohol consumption were factors significantly associated with uncontrolled diabetes ($p<0.05$). These factors were taken up for univariate regression analysis (table 4).

The variables selected for the multivariable logistic regression analysis were physical activity (OR 2.197, 95% CI 1.549 to 3.118), duration of diabetes (5–10 years, OR 0.645, 95% CI 0.449 to 0.925, >10 years, OR 2.024, 95% CI 1.304 to 3.141), diabetic diet (OR 1.655, 95% CI 1.134 to 2.416), regular health check-ups (OR 1.718, 95% CI 1.148 to 2.571), hypertension (OR 2.317, 95% CI 1.603 to 3.294), smoking (OR 3.253, 95% CI 1.830 to 5.785) and alcohol consumption (OR 2.567, 95% CI 1.553 to 4.243). The β-coefficient of these variables were multiplied by 10 and rounded to the nearest integer.

**Table 1** Sociodemographic profile of the study participants

| Sociodemographic factors | | Diabetic status | | | |
|---|---|---|---|---|---|
| | | Controlled N (%) | Uncontrolled N (%) | $\chi^2$ value | P value |
| Age (years) | 20–40 | 32 (14.7) | 41 (12.5) | 2.293 | 0.540 |
| | 41–60 | 115 (52.8) | 160 (48.9) | | |
| | 61–80 | 70 (32.1) | 123 (37.6) | | |
| | >81 | 1 (0.5) | 3 (0.9) | | |
| Sex | Male | 120 (55) | 188 (57.5) | 0.319 | 0.572 |
| | Female | 218 (45) | 139 (42.5) | | |
| Education | Professional | 14 (6.4) | 11 (3.4) | 21.150 | **0.002** |
| | Graduate/PG | 32 (14.7) | 26 (8) | | |
| | PUC/diploma | 41 (18.8) | 39 (11.9) | | |
| | High school education | 42 (19.3) | 64 (19.6) | | |
| | Middle school education | 36 (16.5) | 72 (22) | | |
| | Primary school education | 30 (13.8) | 52 (15.9) | | |
| | Illiterate | 23 (10.6) | 63 (19.3) | | |
| Religion | Hindu | 193 (88.5) | 299 (91.4) | 1.258 | 0.533 |
| | Muslim | 17 (7.8) | 19 (5.8) | | |
| | Christian | 8 (3.7) | 9 (2.8) | | |

Bold p-values indicate statistically significant results.
PUC, pre-university course.

**Table 2** Medical and personal characteristics of the study participants

| Sociodemographic factors | | Diabetic status | | | |
|---|---|---|---|---|---|
| | | Controlled N (%) | Uncontrolled N (%) | $\chi^2$ value | P value |
| Regular physical activity | Yes | 133 (61) | 136 (41.6) | 19.733 | **<0.001** |
| | No | 85 (39) | 191 (58.4) | | |
| Duration of diabetes | <5 years | 34 (15.6) | 46 (14.1) | 10.158 | **0.006** |
| | 5–10 years | 150 (68.8) | 192 (58.7) | | |
| | >10 years | 34 (15.6) | 89 (27.2) | | |
| Follow regular diabetic diet | Yes | 162 (74.3) | 208 (63.6) | 6.8740 | **0.009** |
| | No | 56 (25.7) | 119 (36.4) | | |
| Regular health check-ups | ≤3 months | 173 (79.4%) | 226 (69.1) | 7.000 | **0.008** |
| | >3 months | 45 (20.6) | 101 (30.9) | | |
| Hypertension | Yes | 101 (46.3) | 218 (66.7) | 22.287 | **<0.001** |
| | No | 117 (53.7) | 109 (33.3) | | |
| Dyslipidaemia | Yes | 84 (38.5) | 154 (47.1) | 3.899 | **0.048** |
| | No | 134 (61.5) | 173 (52.9) | | |
| Smoking | Yes | 16 (7.3) | 67 (20.5) | 17.520 | **<0.001** |
| | No | 202 (92.7) | 260 (79.5) | | |
| Alcohol | Yes | 23 (10.6) | 76 (23.2) | 14.172 | **<0.001** |
| | No | 195 (89.4) | 251 (76.8) | | |

Bold p-values indicate statistically significant results.

**Table 3** Anthropometric details of the participants

| Anthropometric details | | Diabetic status | | | | $\chi^2$ value | P value |
|---|---|---|---|---|---|---|---|
| | | Controlled | | Uncontrolled | | | |
| | | N | % | N | % | | |
| BMI | Underweight | 5 | 2.3 | 5 | 1.5 | 2.011 | 0.570 |
| | Normal | 65 | 29.8 | 106 | 32.4 | | |
| | Overweight | 62 | 28.4 | 78 | 23.9 | | |
| | Obese | 86 | 39.4 | 138 | 42.2 | | |
| Waist circumference | ≤102 cm in males and <88 in females | 153 | 70.2 | 215 | 65.7 | 1.173 | 0.279 |
| | >102 cm in males and >88 in females | 65 | 29.8 | 112 | 34.3 | | |
| Waist hip ratio | <0.90 for males and <0.85 for females | 7 | 3.2 | 8 | 2.4 | 0.286 | 0.593 |
| | ≥0.90 for males and ≥0.85 for females | 211 | 96.8 | 319 | 97.6 | | |

BMI, body mass index.

Thus, the final risk score for predicting uncontrolled T2DM was developed (table 5).

For an optimum cut-off point of >13.50, the risk assessment model showed a moderate sensitivity of 71.3%, specificity of 61%, PPV of 73.2% and NPV of 58.3%. The ROC curve was plotted for the model with an AUC of 0.726, 95% CI 0.683 to 0.769 (figure 2).

### Model validation

The validity of the risk score was assessed on data collected from patients with T2DM residing in urban Mysuru. Out of the 21 urban PHCs in Mysuru taluk, 1 PHC was selected through the random sampling method (table of random number method—Urban Primary Health

**Table 4** Univariate regression analysis of risk factors for uncontrolled type 2 diabetes

| Variables | Category | Crude OR | 95% CI | P value |
|---|---|---|---|---|
| Education | Professional or honours | 1 | | |
| | Graduate/PG | 1.034 | 0.402 to 2.658 | 0.945 |
| | PUC/diploma | 0.211 | 0.491 to 2.987 | 0.678 |
| | High school education | 0.939 | 0.804 to 4.678 | 0.140 |
| | Middle school education | 2.545 | 1.050 to 6.169 | **0.039** |
| | Primary school education | 2.206 | 0.889 to 5.473 | 0.088 |
| | Illiterate | 3.486 | 1.385 to 8.773 | **0.008** |
| Regular physical activity | Yes | 1 | | |
| | No | 2.197 | 1.549 to 3.118 | **<0.001** |
| Duration of diabetes | <5 years | 1 | | |
| | 5–10 years | 0.645 | 0.449 to 0.925 | **0.017** |
| | >10 years | 2.024 | 1.304 to 3.141 | **0.002** |
| Follow regular diabetic diet | Yes | 1 | | |
| | No | 1.655 | 1.134 to 2.416 | **0.009** |
| Regular health check-ups | Yes | 1 | | |
| | No | 1.718 | 1.148 to 2.571 | **0.009** |
| Hypertension | No | 1 | | |
| | Yes | 2.317 | 1.630 to 3.294 | **<0.001** |
| Smoking | No | 1 | | |
| | Yes | 3.253 | 1.830 to 5.785 | **<0.001** |
| Alcohol | No | 1 | | |
| | Yes | 2.567 | 1.553 to 4.243 | **<0.001** |

Bold p-values indicate statistically significant results.
PUC, pre-university course.

**Table 5** Multivariable regression analysis of risk factors for uncontrolled type 2 diabetes

| Variables | Category | β-coefficient | Adjusted OR | 95% CI | P value | Score |
|---|---|---|---|---|---|---|
| Regular physical activity | Yes | Reference | 1 | | | 0 |
| | No | 0.764 | 2.148 | 1.475 to 3.127 | **<0.001** | 8 |
| Duration of diseases | <5 years | Reference | 1 | | | 0 |
| | 5–10 years | −0.369 | 0.691 | 0.466 to 1.026 | 0.067 | 0 |
| | >10 years | 0.640 | 1.896 | 1.188 to 3.024 | **0.007** | 6 |
| Follow regular diabetic diet | Yes | Reference | 1 | | | 0 |
| | No | 0.446 | 1.563 | 1.033 to 2.365 | **0.035** | 4 |
| Regular health check-ups | Yes | Reference | 1 | | | 0 |
| | No | 0.488 | 1.630 | 1.050 to 2.530 | **0.00** | 5 |
| Hypertension | No | Reference | 1 | | | 0 |
| | Yes | 0.778 | 2.177 | 1.491 to 3.180 | **<0.001** | 8 |
| Smoking | No | Reference | 1 | | | 0 |
| | Yes | 1.099 | 3.001 | 1.611 to 5.588 | **0.001** | 11 |
| Alcohol | No | Reference | 1 | | | 0 |
| | Yes | 0.793 | 2.209 | 1.277 to 3.822 | **0.005** | 8 |
| Cut-off point | | | | | | **>13.50** |

The β-coefficient was multiplied by 10 and rounded to the nearest integer to determine the score for every variable in the model. A score >13.50 indicated a high risk for having uncontrolled diabetes.
Bold p-values indicate statistically significant results.

Centre Bannimantap). The data were collected from the patients (n=370) when they came for routine health check-ups. Out of the 370, 230 (62.1%) were males and 140 (37.9%) were females. The mean age of the study participants was 55.48±12.26 years. The risk score was applied to these data, which showed a slightly decreased AUC value of 0.700, 95% CI 0.653 to 0.746. The cut-off point based on maximum sensitivity and specificity was the same at 13.50. The sensitivity, specificity, PPV and NPV at this cut-off point were 70.2%, 62%, 74.8% and 56.4%, respectively (table 6).

The risk model was later made into an online web-based tool named 'Diabetes Care' for the assessment of uncontrolled diabetes (https://www.diabetes-care.co.in/). The website provides information about the disease and its prevention. It can also calculate the patient's body mass index (BMI) and the amount of calories consumed. Thus, the website provides detailed information regarding the disease and lifestyle modification, risk prediction and prognosis of the disease for the affected and precautionary management of its acute and chronic complications.

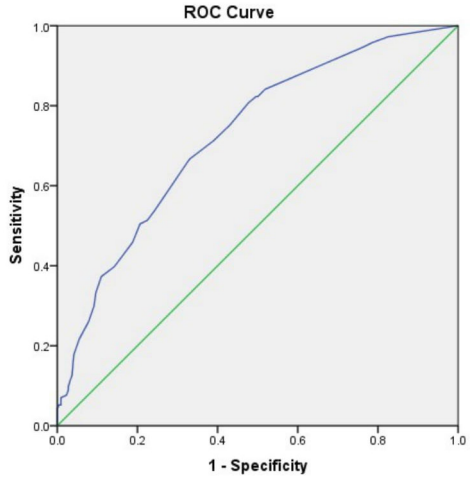


**Figure 2** ROC curve showing the performance of risk assessment tool in predicting uncontrolled diabetes. ROC, receiver-operating characteristic.

## DISCUSSION

Diabetes has already become a leading threat to public health globally in LMICs like India, where the burden has risen significantly in recent decades and will continue to rise in the coming decades. This could greatly influence morbidity and mortality associated with diabetes and, thus, the overall healthcare expenditure in India. A multifaceted approach is required to stop the spread of diabetes and its related complications, including early detection of diabetes, screening for its complications, providing optimal care at all levels of care for those who already have the disease and primary prevention of diabetes in those with pre-diabetes.[3]

This exploratory study was done among patients with T2DM to develop and validate a non-invasive and self-administered risk assessment tool for patients with uncontrolled T2DM. Our study reported the prevalence of uncontrolled diabetes to be 59.9%. A study done by Ganesh *et al*[5] reported the prevalence of uncontrolled diabetes was 65.4% which was higher than our findings. In a study by Mahapatra *et al*,[15] the prevalence of

Table 6 Performance of the risk assessment tool for uncontrolled type 3 diabetes

| Model population | AUC | Cut-off | Sensitivity | Specificity | PPV | NPV |
|---|---|---|---|---|---|---|
| Overall | 0.717 (0.673–0.761) | 13.50 | 71.3% (67.5%–75.1%) | 61% (56.8%–65.1%) | 73.2% (69.3%–76.7%) | 58.3% (54.1%–62.4%) |
| Urban Mysuru | 0.700 (0.653–0.746) | 13.50 | 70.2% (69.9%–74.6%) | 62% (56.9%–66.8%) | 74.8% (70.1%–78.9%) | 56.4% (51.3%–61.4%) |

AUC, area under the curve; NPV, negative predictive value; PPV, positive predictive value.

uncontrolled diabetes was 46.43% and in a study by Kanungo *et al*,[16] the prevalence was 47% which was lesser when compared with our study findings. The difference in the prevalence of uncontrolled diabetes can be attributed to different study settings, distinct criteria for uncontrolled diabetes and different geographical locations.

Our study highlighted the factors affecting uncontrolled diabetes. Taking education as a factor, a significant difference was observed as 63 (19.3%) illiterates had uncontrolled diabetes and 23 (10.6%) had diabetes under control and among professionals, 11 (3.4%) had uncontrolled diabetes, contrary to 14 (6.4%) with controlled diabetes. Patients with a low education level have more complications and they are also more unaware of their hypoglycaemic symptoms causing severe complications.[17]

Regular exercise was thought to be crucial for managing DM as it regulates the blood glucose levels and actions of insulin. Our study revealed that out of 327 uncontrolled diabetics, 136 (41.6%) of them had a regular physical activity while 133 (61%) people who had a history of regular physical activity were found to have their glucose levels controlled. In a study done by Rasheed *et al*,[18] it was found that 27% with uncontrolled diabetes and 40% of people with controlled diabetics had a regular physical activity, which was lesser compared with our findings.

Hypertension is an important risk factor in DM. In our study, 218 (66.4%) individuals with uncontrolled diabetes had associated hypertension and 101 (46.3%) among controlled diabetes had hypertension. In another study by Rasheed *et al*,[18] in a controlled group of DM 30% of individuals had a history of hypertension while in the uncontrolled group hypertension was present in 47% of individuals and was lesser than our study findings.

In our study, we found out that 58.7% and 27.2% of subjects with a disease duration of 5–10 years and more than 10 years belong to the uncontrolled diabetic groups, respectively, and we can see that as the duration of the disease increases the diabetes is becoming uncontrolled. Another study done by Badedi *et al* found that individuals with lower HbA1c followed the diabetes diet recommendations and took their medications as prescribed by doctors. On the other hand, patients with poor glycaemic control frequently took multiple medications and had diabetes for a longer period. A longer duration of diabetes and polypharmacy are known to be significantly linked to poor glycaemic control.[19] Early detection and effective control of diabetes are the main management priorities. According to studies, diabetes control deteriorates as the disease duration exceeds 10 years.[5]

Among the subjects in our study, 74.3% followed a regular diabetic diet and had their diabetes status under control and 36.4% of uncontrolled diabetics were not following a proper diabetic diet. Likewise, 79.4% of diabetics who had regular health check-ups within 3 months had their glycaemic level under control and 30.9% of uncontrolled diabetics had their check-ups only after 3 months. The American Diabetes Association defines self-dietary management as the essential first step in providing diabetics with the knowledge and skills they need about treatment, nutritional considerations, medications and complications.[20]

In our study among the diabetic subjects, 15.2% were smokers and 18.2% were alcoholics. We observed diabetics who smoked and consumed alcohol, there was a higher rate of uncontrolled diabetes than their counterparts. A prospective study of cigarette smoking, alcohol use and risk of diabetes in men, done by Rimm *et al*, observed lower rates of diabetes among men who did not smoke and among men who consumed alcohol. After simultaneously controlling for each other and other known predictors of non-insulin-dependent DM, the risk of drinking alcohol and smoking became more pronounced.[21]

In our study, education of the participants, physical activity, duration of diabetes, type of medication, diabetic diet, regular health check-ups, history of hypertension and dyslipidaemia, smoking history and alcohol consumption were factors that had a significant association with uncontrolled diabetes ($p<0.05$). These factors were taken up for univariate regression analysis. After the analysis, variables such as physical activity, duration of diabetes, diabetic diet, regular health check-ups, history of hypertension and dyslipidaemia, smoking history and alcohol consumption were taken up for multivariable regression followed by the development of final risk score for predicting uncontrolled diabetes with a cut-off point of >13.50 with a sensitivity of 71.3% and specificity of 61%, PPV 73.2% and NPV of 58.3%. The ROC curve was plotted for the predictive model with an AUC of 0.726.

In a study by Lindström and Tuomilehto,[22] to develop a risk score for diabetes—age, BMI, waist circumference, history of antihypertensive drug treatment and high

blood glucose, physical activity, and daily consumption of fruits, berries or vegetables were selected as categorical variables. The Diabetes Risk Score value varied from 0 to 20. To predict drug-treated diabetes, the score value ≥9 had a sensitivity of 0.78 and 0.81, specificity of 0.77 and 0.76, and PPVs of 0.13 and 0.05 in the 1987 and 1992 cohorts, respectively. The Diabetes Risk Score was designed to be a screening tool for identifying high-risk subjects and increasing awareness of the modifiable risk factors and healthy lifestyles.

Later in our study, the validity of the risk score was assessed on data collected from patients with T2DM residing in urban Mysuru. The risk score was applied to this data which showed a slightly decreased AUC value of 0.700, 95% CI 0.653 to 0.746. The cut-off point based on maximum sensitivity and specificity was the same at 13.50. The sensitivity, specificity, PPV and NPV at this cut-off point were 70.2%, 62%, 74.8% and 56.4%, respectively. The study by Lindström and Tuomilehto[22] analysed the performance of the Diabetes Risk Score cross-sectionally in identifying subjects who had either fasting or 2-hour glucose levels exceeding the threshold of diabetes. The ROC curves (not shown) indicated the good performance of the Diabetes Risk Score also in the cross-sectional setting (AUC=0.80 for both surveys). For cut point Diabetes Risk Score of ≥9, sensitivity was 0.77 (95% CI 0.66 to 0.85) and 0.76 (95% CI 0.67 to 0.83), specificity was 0.66 (95% CI 0.64 to 0.68) and 0.68 (95% CI 0.66 to 0.70), PPV was 0.07 (95% CI 0.06 to 0.09) and 0.12 (95% CI 0.10 to 0.15), and NPV (the probability of not having diabetic glucose levels if Diabetes Risk Score was <9) was 0.99 (95% CI 0.98 to 0.99) and 0.98 (95% CI 0.97 to 0.99) in the 1987 and 1992 oral glucose tolerance tests, respectively.

Another study was done by Mohan *et al*[23] to develop and validate a simplified Indian Diabetes Risk Score (IDRS) for detecting undiagnosed diabetes in India. IDRS used four risk factors: age, abdominal obesity, family history of diabetes and physical activity. Beta coefficients were derived from a multiple logistic regression analysis using undiagnosed diabetes as the dependent variable. The beta coefficients were modified to obtain a maximum possible score of 100. ROC curves were constructed to identify the optimum value of IDRS for detecting diabetes by WHO consulting group criteria. The AUC for ROC was 0.698 (95% CI 0.663 to 0.733). An IDRS value ≥60 had the optimum sensitivity (72.5%) and specificity (60.1%) for determining undiagnosed diabetes with a PPV of 17.0%, NPV of 95.1% and accuracy of 61.3%.

A study was done by Adhikari *et al*[24] to validate the MDRF-IDRS in a south Indian population in coastal Karnataka, in which IDRS score of ≥60 had the best sensitivity (62.2%) and specificity (73.7%) for detecting undiagnosed diabetes in this community. The MDRF-IDRS was calculated using age, family history of diabetes, physical activity and waist measurement. ROC curves were constructed to identify the optimum value (≥60%) of IDRS for determining diabetes as diagnosed using WHO consulting group criteria.

Our study was subject to various limitations. First, its base population may not be entirely representative of South Indians overall, as it is based on people living in Southern Karnataka. Second, a small sample size was employed in the data collection process. It is necessary to conduct more research with bigger sample sizes. Finally, the results show low sensitivity, specificity, PPV and NPV. More research must be done with bigger sample sizes and improved sensitivity, specificity, PPV and NPV.

## CONCLUSION

This study developed 'Diabetes Care' which is a web-based simple, non-invasive and inexpensive tool for identifying individuals at risk of developing uncontrolled T2DM in the future. The website also provides detailed information regarding the disease and lifestyle modification, risk prediction and prognosis of the disease for the affected and precautionary management of its acute and chronic complications. This tool is specifically designed for the population of southern Karnataka.

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