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Original Article

Targeted screening for prediabetes and undiagnosed diabetes in a community setting in India

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ABSTRACT

Background and objectives: Data to support the use of risk scores in screening programs to detect people with prediabetes and undiagnosed diabetes in low- and middle-income countries are limited. We evaluated a targeted screening program involving a diabetes risk score in a community setting in India in terms of its uptake, yield, and costs.

Methods: In the Kerala Diabetes Prevention Program, 2586 individuals (age 30–60 years) without known diabetes were screened using a two-step procedure. Step 1: screening with the Indian Diabetes Risk Score at participants' homes by trained non-medical staff. Step 2: oral glucose tolerance test (OGTT) among those with IDRS score ≥60 ("screen-positive") at community-based clinics. Screening costs were expressed in 2013 US dollars.

Results: 96.3% of those invited for the IDRS screening consented and 79.1% of screen-positives attended clinics for an OGTT. Older age and male gender were associated with higher IDRS uptake. Female gender, higher monthly household expenditure, and higher IDRS score were associated with higher OGTT uptake. The number needed to screen (yield) to detect one person with prediabetes and undiagnosed diabetes was two and six, respectively. The average screening cost of identifying one person with prediabetes and undiagnosed diabetes was $33.8 and $116.5, respectively.

Conclusion: This targeted screening program had a high uptake and high yield for prediabetes and undiagnosed diabetes in a community setting in India. Alternative strategies are likely required to enhance the uptake of screening in certain groups.

1. Introduction

Type 2 diabetes has emerged as a major public health problem worldwide [1]. According to the International Diabetes Federation, in 2017, there were 425 million people with diabetes, and the global healthcare expenditure on diabetes was estimated at 727 billion USD [1]. People with type 2 diabetes may remain undiagnosed for many years, and undiagnosed diabetes is associated with micro- and macro-vascular complications [2]. Early diagnosis and treatment of type 2 diabetes are likely to reduce cardiovascular morbidity and mortality [3]. The natural history of type 2 diabetes is well understood [4], and effective treatment is available for those with established diabetes [5]. There is compelling evidence to show that type 2 diabetes can be prevented with lifestyle interventions in people with prediabetes who are at high risk of developing type 2 diabetes [6]. Concurrent screening for type 2 diabetes and prediabetes, with appropriate intervention for people with prediabetes, is the most cost-effective strategy [7]. These have provided a strong rationale to screen for prediabetes and undiagnosed diabetes.

Mass screening for prediabetes and type 2 diabetes with an oral glucose tolerance test (OGTT) is generally not recommended because such a procedure is invasive, expensive, and inconvenient

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to individuals and healthcare providers [8]. Several international organizations and expert groups advise that screening with an OGTT should be targeted to high-risk individuals identified using a diabetes risk score [5,9,10]. Studies have shown that screening a population with a diabetes risk score followed by an OGTT would cost less [11], and have higher uptake and yield compared to mass screening with an OGTT [12]. Furthermore, modeling studies suggest that such a targeted screening program is the most cost-effective way of identifying people with prediabetes and type 2 diabetes [13].

Much of the evidence on the uptake, yield, and costs of screening programs involving diabetes risk scores have come from studies conducted in clinical settings of high-income countries [12,14–20]. These may not be necessarily extrapolated to low- and middle-income countries (LMICs), where the burden of prediabetes and diabetes is substantial, and people have limited access to healthcare facilities [21]. The Kerala Diabetes Prevention Program (K-DPP) was a cluster-randomized controlled trial of a peer-support lifestyle intervention for the prevention of type 2 diabetes in India [22,23]. K-DPP involved two phases: a screening program to identify high-risk individuals (diabetes risk score followed by an OGTT) and an intervention program for the identified high-risk individuals. In this paper, we aimed to examine the screening program in terms of the following: (1) uptake and factors influencing the uptake of each step of the screening program; (2) yield of the screening program, measured as the number needed to screen (NNS) to detect one person with prediabetes and undiagnosed diabetes; and (3) average cost to identify one person with prediabetes and undiagnosed diabetes.

2. Methods

2.1. Study design

The study design of K-DPP has been described in detail elsewhere [23]. Briefly, the trial was conducted in 60 randomly selected polling areas (electoral divisions) of Neyyattinkara *taluk* (sub-district) in Trivandrum district, Kerala state. Individuals (aged 30–60 years) selected randomly from the electoral roll of the 60 polling areas were contacted through home visits by trained non-medical staff, and invited to participate in the screening program, and subsequently in the trial. For those who were not reachable at the first instance, at least two more home visits were made on different days before considering them as non-responders. Eligibility criteria included literacy in the local language (Malayalam), no history of diabetes or any other major chronic illness, not being pregnant, and currently not taking medications known to affect glucose tolerance. Eligible individuals underwent a two-step screening program as described below.

2.2. Screening program

2.2.1. Step 1: Indian Diabetes Risk Score

The first screening step consisted of the administration of the Indian Diabetes Risk Score (IDRS) [24]. The IDRS is a simple non-invasive diabetes risk score, which includes questions about age, physical activity (regular exercise or strenuous work or both) and family history of diabetes (parents), and the measurement of waist circumference. The total IDRS score is a sum of contributions from each variable and ranges between 0 and 100. The IDRS is the most popular risk score in India, with validation studies conducted in several states of India [25–30], and in a simulated nationally representative Indian population [31]. In our study region, an IDRS score of $\geq$60 has been shown to identify people with diabetes with a sensitivity of 85.7%, a specificity of 59.4%, and an accuracy of 80% [30]. Trained non-medical field staff (educated up to secondary school or more) administered the IDRS. Staff members were given initial training, with four further training sessions at 3-month intervals, each lasting for half a day. Participants with an IDRS score $\geq$60 ("screen-positive") were invited for an OGTT. Along with the administration of the IDRS, data on some demographic characteristics (gender, monthly household expenditure, and household size) were collected using a questionnaire.

2.2.2. Step 2: oral glucose tolerance test

The second screening step consisted of a 2-hr 75-g OGTT. For this, participants attended clinics conducted in their polling areas using locally based venues (e.g., schools, community halls, health centers). Clinics were held only during weekends. Participants received a telephone reminder on the day before their scheduled clinic date. The OGTT was performed according to the World Health Organization guidelines [32]. A venous blood sample was taken after an overnight fast for at least eight hours and a second blood sample was collected two hours after oral ingestion of 75-g glucose dissolved in 250–300 ml of water. Blood samples were collected in fluoridated tubes and centrifuged within 30 min of collection and transported in boxes with dry ice to a laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) [33]. Plasma aliquots were stored at −20 °C until conduction of the analysis. Plasma glucose was analyzed using the hexokinase method on a COBAS 6000 analyzer, with kits supplied from Roche Diagnostics, Switzerland. For external quality control, blood samples of 48 randomly selected participants were sent to a different laboratory accredited by NABL [33] and by the College of American Pathologists [34]. The intra-class correlation coefficient (ICC) [35], a measure of reliability, between the two laboratories for fasting plasma glucose (FPG) was 0.964 and for 2-hr plasma glucose (2-hr PG) was 0.990. Participants were classified as having normoglycemia (fasting plasma glucose (FPG) < 5.6 mmol/l and 2-hr plasma glucose (2-hr PG) < 7.8 mmol/l), prediabetes (impaired fasting glucose (IFG): FPG 5.6–6.9 mmol/l and 2-hr PG < 7.8 mmol/l or impaired glucose tolerance (IGT): FPG <7.0 mmol/l and 2-hr PG 7.8–11.0 mmol/l)) or diabetes (FPG $\geq$7.0 mmol/l and/or 2-hr PG $\geq$ 11.1 mmol/l), according to the American Diabetes Association (ADA) criteria [5]. Initial non-attendees were invited to attend follow-up clinics.

2.3. Statistical analysis

Data were summarized using mean and standard deviation for continuous variables, and using frequency and percentage for categorical variables. Uptake was calculated by dividing the number of individuals responding to the screening invitation by the total number invited [12]. It was estimated separately for each screening step. The factors associated with uptake of each screening step were examined using logistic regression, with p values and 95% confidence intervals (CIs) based on Huber-White standard errors that were adjusted for clustering by polling areas. All variables tested in univariate analysis (irrespective of their significance) were included in a multivariate model. The results of the multivariate model were presented as odds ratios (ORs), 95% CIs, and p values. The yield was measured using the NNS (and 95% CI), which was calculated by dividing the total number screened using the OGTT with the number of individuals diagnosed with prediabetes (or diabetes) on the OGTT [12]. Screening costs included personnel costs, materials costs, and operations costs. Personnel costs were based on the actual salary (or remuneration) paid to the staff. Cost of materials (IDRS and OGTT) and operations (training sessions for field staff and LRPs, travel, rent for clinic venues, phone calls, and overheads) were estimated based on the actual expenditure for

those items. The cost figures were obtained from the finance registers. The cost estimates in Indian Rupees (INR) were converted to US$ using an exchange rate of INR 58.6 = 1US$ for the year 2013 [36]. A two-sided p-value less than 0.05 was considered statistically significant. All analyses were performed using Microsoft Excel 2016 (Microsoft Corporation, Redmond, Washington, USA) or Stata version 14.2 (Stata Corp LP, College Station, TX, USA).

Ethics approval

K-DPP was approved by the Health Ministry Screening Committee of the Government of India, and ethics committees of the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCT/IEC-333/May 2011), Trivandrum, India, and Monash University (CF11/0457–2011000194) and The University of Melbourne (1441736) in Australia. Written informed consent was obtained from all study participants.

3. Results

The screening was undertaken from January 20, 2013, to October 27, 2013. Fig. 1 shows the flow of participants through the two-step screening program. After excluding those not satisfying the age criteria (n = 137), 3552 were invited for the IDRS screening, of which, 3421 (96.3%) consented. Of these, 835 (24.4%) did not satisfy the eligibility criteria, and 2586 (75.6%) were screened with the IDRS. On average, it took five minutes to administer the IDRS for each participant. Among those screened with the IDRS, 1529 (59.1%) were identified as screen-positives and therefore invited to attend community-based clinics for an OGTT. Of these, 1209 responded (79.1%). The median interval between the two screening steps was three days (interquartile range: two to four days).

Table 1 shows the factors associated with uptake of each step of the screening program. In the multivariate model, older age (OR 1.54 for 41–50 years; OR 2.36 for 51–60 years versus 30–40 years) and male gender (OR 1.98) were associated with higher IDRS uptake. Female gender (OR 1.57), higher monthly household expenditure (OR 1.82 for the third tertile; OR 1.81 for the second tertile versus the first tertile) and higher IDRS score (OR 1.73 for ≥80 points versus <80 points) were associated with higher OGTT uptake

Of those who underwent an OGTT (n = 1209), after excluding those with normoglycemia (n = 312), 695 (57.5%) had prediabetes and 202 (16.7%) had diabetes. Thus, the NNS was two for prediabetes and six for undiagnosed diabetes. Table 2 shows the K-DPP screening costs. The total screening cost was $23,525.3. Personnel cost was the major cost contributor (63.5%) of the total costs followed by operations cost (20.0%), and materials cost (16.5%). The average cost to identify one person with prediabetes and undiagnosed diabetes was $33.8 and $116.5, respectively.

4. Discussion

To our knowledge, this is the first study from India to evaluate a targeted screening procedure involving a diabetes risk score in terms of its uptake, yield and cost for identifying people with prediabetes and undiagnosed diabetes in a community setting.

The uptake of the IDRS (96.3%) was higher than the uptake seen in other studies using diabetes risk scores (e.g., Danish Diabetes

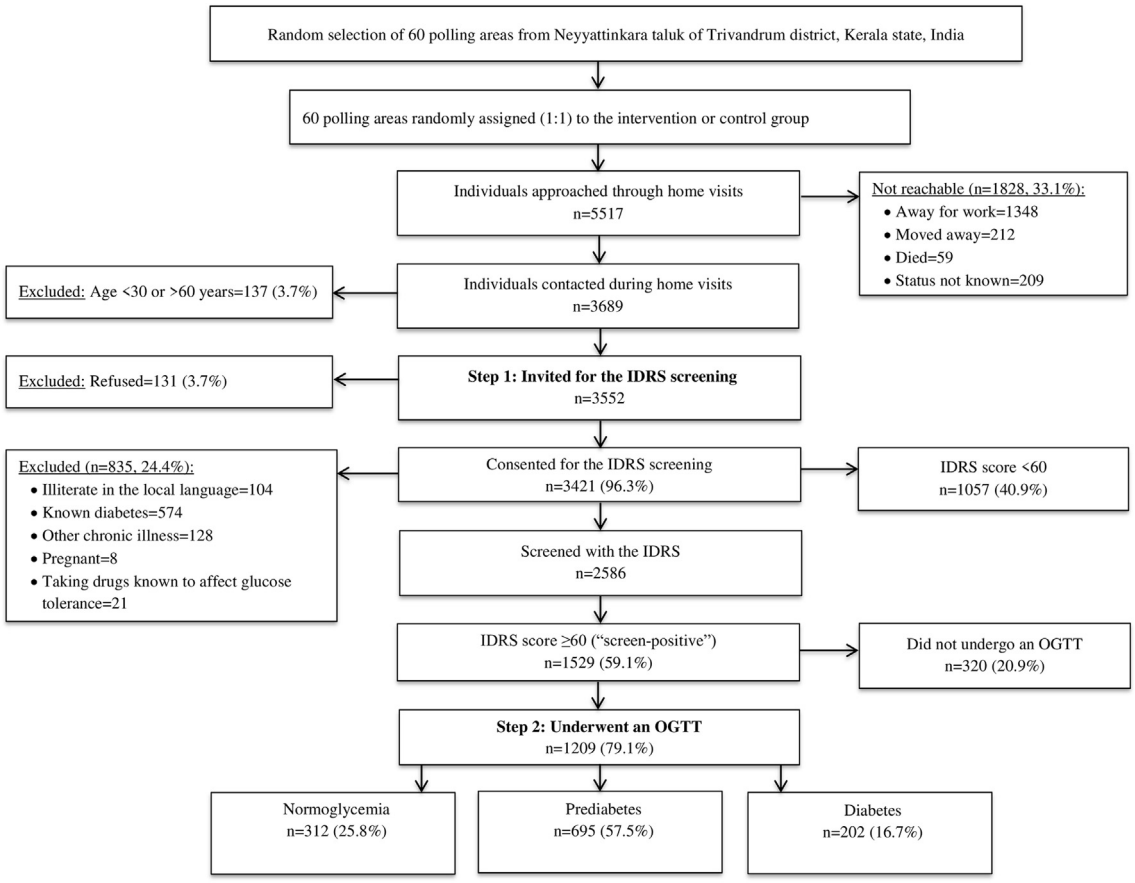

Fig. 1. Flowchart showing the flow of participants through the two-step screening program.

Table 1
Factors associated with uptake of each step of the screening program.

	n	Non-responders[a]	n	Responders[a]	Unadjusted OR (95% CI)	P[b]	Adjusted OR (95% CI)	P[b]
Step 1: IDRS								
N		131		3421				
Age (years), n (%)								
30–40	125	57 (43.5)	3374	1054 (30.8)	1.00		1.00	
41–50		45 (34.4)		1287 (37.6)	1.55 (1.04–2.31)	0.032	1.54 (1.03–2.30)	0.034
51–60		23 (17.6)		1033 (30.2)	2.43 (1.49–3.97)	<0.001	2.36 (1.45–3.87)	0.001
Gender, n (%)								
Female	131	69 (52.7)	3421	1209 (35.3)	1.00	<0.001	1.00	
Male		62 (47.3)		2212 (64.7)	2.04 (1.43–2.89)		1.98 (1.38–2.83)	<0.001
Step 2: OGTT								
N		320		1209				
Age (years), n (%)								
30–40	320	78 (24.4)	1209	326 (27.0)	1.00		1.00	
41–50		133 (41.6)		495 (40.9)	0.89 (0.65–1.22)	0.47	0.92 (0.67–1.26)	0.60
51–60		109 (34.1)		388 (32.1)	0.85 (0.61–1.18)	0.33	0.96 (0.68–1.35)	0.80
Gender, n (%)								
Male	320	216 (67.5)	1209	654 (54.1)	1.00	<0.001	1.00	
Female		104 (32.5)		555 (45.9)	1.76 (1.36–2.29)		1.57 (1.20–2.06)	0.001
Monthly household expenditure tertile, n (%)								
<6000 INR	317	155 (48.4)	1209	395 (32.7)	1.00		1.00	
6000-8000 INR		80 (25.0)		393 (32.5)	1.93 (1.42–2.61)	<0.001	1.82 (1.33–2.49)	<0.001
>8000 INR		82 (25.6)		421 (34.8)	2.01 (1.49–2.72)	<0.001	1.80 (1.32–2.47)	<0.001
Household size,[c] n (%)								
<4	320	89 (27.8)	1208	268 (22.2)	1.00	0.035	1.00	
≥4		231 (72.2)		940 (77.8)	1.35 (1.02–1.79)		1.16 (0.86–1.57)	0.32
IDRS score								
<80	320	284 (88.8)	1209	973 (80.5)	1.00		1.00	
≥80		36 (11.3)		236 (19.5)	1.91 (1.32–2.78)	0.001	1.73 (1.17–2.56)	0.006

OR; odds ratio, CI; confidence interval, IDRS; Indian Diabetes Risk Score, OGTT; oral glucose tolerance test, INR; Indian Rupees. Percentages for some variables may not add up to 100% due to missing data. [a]Non-responders were those who did not undergo that particular screening step, and responders were those who underwent that particular screening step. [b]P value based on Huber-White standard errors that were adjusted for clustering by polling areas in logistic regression analysis. [c]Divided into two categories based on the median value of four.

Table 2
K-DPP screening costs.

Item	Unit	Time (hours)	Unit cost ($)	Total cost ($)
Personnel				
Project manager	1	334.0	2.5/hr	831.2
Project assistant	1	391.8	1.1/hr	417.9
Field assistant	1	240.0	0.9/hr	204.8
Field staff	10	12521.5	0.8/hr	10432.2
Local resource person (LRP)	60	2431.5	1.3/hr	3045.1
Phlebotomist[a]	3	945.0	0/hr	0
Total personnel cost				14931.2
Materials				
IDRS	2586		0.03/questionnaire	66.2
OGTT[b]	1029		3.2/test	3816.8
Total materials cost				3883.0
Operations				
Training sessions for field staff and LRPs	5			450.2
Rent for clinic venues				87.4
Phone calls				502.0
Travel costs				2123.1
Overheads				1548.5
Total operations cost				4711.2
Total cost				**23525.3**
Cost to identify one person with diabetes				116.5
Cost to identify one person with prediabetes				33.8

IDRS, Indian Diabetes Risk Score; OGTT, oral glucose tolerance test.
[a] Cost of phlebotomist's time was included in the OGTT test cost.
[b] Cost of OGTT test includes cost of phlebotomist's time, instruments and reagents. Costs are expressed in 2013 US$.

Risk Score, Finnish Diabetes Risk Score) [37,38] This might be explained by the method of invitation: face-to-face in our study versus postal invite [37] or online completion [38] in those studies. The uptake of the OGTT (79.1%) in our study was higher than the uptake found in screening studies conducted in clinical practices [37–39] and similar to that reported in studies from workplaces [40] The high OGTT uptake in our study was probably due to the following factors. First, the risk stratification by the IDRS might have positively influenced the response rate for the OGTT. The ADDITION-Europe study showed that the attendance rates for blood tests were high after risk stratification by a risk score in the general practices of Denmark and Cambridge [41] Second,

participants were invited to undergo an OGTT in clinics conducted in the local community, with venues being easily accessible by foot or public transport. Previous studies have shown that screening uptake was negatively influenced by longer distance an individual must travel to the screening site[42]. Third, the time interval between the two screening steps was minimal (median interval was three days). The long lag time between the screening steps resulted in dropouts in a recent diabetes prevention trial in India [43]. Finally, we used 'assertive tracking' measures including telephone reminders [44] and follow-up clinics to maximize the uptake. However, follow-up clinics had lower uptake (50%) than the initial clinics (78.2%). In assertive tracking measures, the uptake will usually be highest for the first tier, with subsequent tiers having lower uptakes [45].

Understanding the factors influencing the uptake of screening would enable more appropriate targeting of screening programs [14]. Younger individuals (30–40 years) were less likely to attend for the IDRS screening, which is in line with other screening studies using risk scores [14]. It is noteworthy to mention here that the prevalence of diabetes among people in India begins to increase at the age of 25 years [46]. Therefore, it is important to motivate and engage younger adults to participate in screening programs. The reasons behind the finding that males were more likely to undergo IDRS screening but not the OGTT screening are not clear. A possible explanation could be that in our study region, males (who are mostly daily wage earners) generally leave for work early in the morning, thereby impeding them from attending clinics in a fasting state and to wait for two hours for the OGTT. On the other hand, the IDRS screening took only around five minutes to complete, and this was done at the households during late evening hours after males had returned from work. Thus, it might be surmised that the lengthy nature of the OGTT screening was a barrier for males to attend the clinics. Screening at worksites is required to enhance the OGTT uptake among males.

A recent systematic review and meta-analysis showed that the NNS for prediabetes and diabetes reduces as the number of screening step increases [12]. Consistent with this, the NNS in our study for prediabetes and diabetes was low at two and six, respectively. Our previous research [25] and other studies [11,47] evaluating the performance of the IDRS have shown that the prevalence of prediabetes and diabetes was lower in those with low or moderate risk (i.e., IDRS score <60) compared to those with high risk (i.e., IDRS score ≥60). Thus, compared to mass screening with the OGTT, it is likely that the NNS would be lower by risk stratification with the IDRS.

The average cost of identifying one person with prediabetes and undiagnosed diabetes was $33.8 and $116.5, respectively. In real-world clinical practice in India, the screening costs would be lower than these, as community health workers and healthcare providers will screen and identify people with prediabetes and diabetes as part of their routine healthcare service [48]. Of note, personnel cost constituted nearly two-thirds of the total screening costs in our study. Furthermore, the one-off costs (e.g., training of field staff, and printing charges for IDRS) would be distributed over a much larger number of individuals as a result of economies of scale.

Our study has certain strengths. The study sample was sufficiently large and community-based. In India, it is essential to implement community-based screening programs as opportunistic screening alone is not enough to identify people with undiagnosed diabetes [49]. We used OGTT as the gold standard test for diagnosing prediabetes and diabetes. Although a repeat OGTT test is required to confirm the diagnosis in the absence of symptoms [5], a single OGTT is commonly accepted in screening studies, and it also reflects the real-life screening programs. The ICC for plasma glucose values between the local and external quality control laboratories was very high (almost 1.0), indicating high reliability. However, there are some limitations in this study. Since the screening program was the first phase of a diabetes prevention trial, we had to exclude certain individuals who were not suitable for the intervention program. These individuals will not be excluded if the screening program has to be implemented on its own. Data for some variables that are known to influence the OGTT uptake (e.g., body mass index, use of anti-hypertensive medications and risk perception) [14,15] were not available for the OGTT non-attendees in our study.

To conclude, a targeted screening program using a simple and easy to administer diabetes risk score had a high uptake and high yield for prediabetes and undiagnosed diabetes in a community setting in India. Thus, screening programs in India could target high-risk individuals identified using the IDRS. However, the cost-effectiveness of this screening strategy needs evaluation. Future program planners implementing community-based screening programs should also consider screening at worksites to enhance the reach of males and working individuals. The screening costs reported in our study could be used for designing and implementing community-based screening programs in India to detect people with prediabetes and undiagnosed diabetes.

Conflicts of interest

The authors declare no conflict of interests.

Trial registration

Australia and New Zealand Clinical Trials Registry: ACTRN12611000262909.

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