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Estimated risk of cardiovascular events and long-term complications: The projected future of diabetes patients in Delhi from the DEDICOM-II survey

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ABSTRACT

Problem: Despite high prevalence and ethnic susceptibility, limited published estimates are available on long term complication risks among known diabetes patients in India. Hence, we undertook evaluation of the cardiovascular risk of known diabetes patients from Delhi.

Methods: The community-survey was conducted using a probability-proportionate-to-size(systematic) 2-stage cluster design. Thirty areas were selected for a house-to-house survey to recruit 25 to 30 subjects (known diabetes ≥1 year; 35–65 years of age) per area. Scores from the UKPDS 2.1, UKPDS 2.0, Framingham, ASCVD, WHO, NHS and SCORE studies were used for 10-year risk calculation.

Results: We enrolled 843 subjects of which 800 consented for blood sampling. The mean age of the subjects was 53.0(52.1–54.0) years, the mean duration since diagnosis was 7.1(6.7–7.5) years, with 49.8 % women. 61.8 % were hypertensive, 81.5 % were dyslipidaemic and 53.3 % had poor glycaemic control. Although variable, risk engines estimates were consensual in projecting a high ten-year Coronary-Heart-Disease risk of 10–16 %, a stroke risk of 3.7–5.0 %, and a 5.0–5.7% risk of cardiovascular fatality. These risks were 1.5–3 times the 'risk at target levels' suggesting mitigability. Only 9.3 %, 16.0 %, and 30.0 % were taking aspirin, lipid lowering drugs and antihypertensives respectively.

Conclusion: The study highlights the impending impact of, and the scope for improvement in the cardiovascular risk profile of diabetes patients in Delhi, including the use of cardioprotective medications. It strengthens the case for developing and testing potential interventions for improvement.

1. Introduction

Type 2 diabetes mellitus is a rising major public health problem in Delhi, India, and worldwide with an estimated ~5.1 million, 77 million, and 529 million diabetes patients respectively [1,2]. India has been referred to as the "Diabetes Capital of the World" and Delhi has the grim privilege of having the most cases. While the high prevalence of the disease is one factor, the long-term complications of diabetes are a crucial determinant of the years of life left, quality of life, cost of care, psychological well-being, and the overall utility of the individual. Diabetes is known to increase the risk for major cardiovascular events like MI and stroke and microangiopathic chronic conditions like nephropathy, retinopathy, and peripheral vascular disease. Expert bodies like the American Diabetes Association, International Diabetes Federation, and Indian Council of Medical Research have regularly updated guidelines [3–5] for risk factor management in diabetes. Despite the risk and longstanding knowledge of preventive measures, poor control of risk factors in diabetes patients continues to be widely prevalent across the world [6] and especially in India [7]. Further, South Asian/Indian ethnicity is a documented additional risk factor for cardiovascular disease [8,9].

Despite the international focus [10], high prevalence of the disease and higher ethnic susceptibility, limited published estimates are available on long-term complication risks among known diabetes patients from India [11–14]. The usefulness of cardiovascular risk projection amongst diabetes patients lies in its ability to provide an index of quality of care by which one can estimate the extent to which the risk is mitigable by good public health and clinical interventions. While there is limited literature on existing cardiovascular morbidity, risk factor profile, and use of cardioprotective medications in India [15–18], it is sporadic in location, non-comprehensive, focuses on a few morbidities, and is not community based. Additionally, none of these studies are from

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Delhi. To highlight the grim yet preventable fate awaiting diabetes patients in Delhi we had provided cardiovascular risk estimates for diabetes patients in Delhi based on a community survey in 2005. While providing helpful information, this first survey and its related projections were restricted to the higher and middle-income groups and is currently outdated [19]. In 2018–2020 we repeated the study in the same city using the same methodology (DEDICOM-II) [7] while including all socio-economic strata in the second iteration. Much has changed over the last 17 years, with several large cohorts being utilized to provide newer, more comprehensive, and presumably more accurate risk modelling equations/algorithms and the availability of more recent and more representative data from the DEDICOM-II survey. We, therefore, decided to utilise the recently available risk models to analyse the data available from the DEDICOM-II survey to predict long-term diabetes-related morbidity, including cardiovascular risk.

2. Material and methods

2.1. Study population

The Delhi Diabetes COMmunity-II [7] survey was conducted between April 2018 and July 2020 based on socioeconomic category A to G area (Property tax classification). Subjects between the ages of 35 and 65 years with known diabetes for 1 year or more (diagnosed by a registered medical practitioner using at least one blood glucose estimation) were included in the survey. Those with Type 1 diabetes, gestational diabetes, cancer, a renal, hepatic, or intestinal disease requiring ongoing treatment or hospital admission (>1 week in the last 1 year) or inability to communicate (due to mental illness or physical disability) were excluded. A written informed consent form was taken before recruitment. The definitions used in the survey are presented in Appendix 1.

Details of the methodology of the survey have been described in a previous publication [7]. To summarize, a two-stage cluster-randomized sampling approach was used to select 30 of the 150 wards (Stage 1). A random computer-generated seed value was generated, and then wards were selected at a predefined sampling interval (population × 30]/150; Probability-Proportionate-to- Size—systematic method). Population sizes were used from the available census population data [20]. In stage 2, a house-to-house survey was conducted in a randomly selected colony in the ward to identify 40 known diabetes patients sequentially. The research team visited patients identified by the field team to screen for selection criteria. The enrolled subjects completed a standardized pretested questionnaire to determine the quality of diabetes care [7], existing lifetime cardiovascular morbidity, current cardiovascular risk profile, and use of cardiovascular protective agents, including lipid-lowering drugs, aspirin, and antihypertensive agents.

The information recorded included age, sex, ethnicity, education, marital status, medical benefits, annual household income, smoking, alcohol use, duration since diagnosis (DSD), qualification of the Primary Care Provider (PCP), place of healthcare and number of visits to the PCP in the last year. Information on self-reported cardiovascular morbidity (CAD, MI, stroke, foot amputations), use of aspirin, lipid-lowering drugs, and anti-hypertensive agents was collected from records and by interview. Morbidity was recorded using standardized colloquial explanations for individual morbidities by the patient recall and by record review. No standardization/encoding of medical diagnosis or treatment was considered feasible (as in the earlier survey) given the variable and often poor record keeping, poor patient awareness levels and the multiplicity of healthcare delivery systems.

2.2. Ten-year risk projection

The risk projection is a secondary analysis using data from the original community survey and does not overlap with the findings of the published paper [7]. Risk equations/scores from various sources such as the Framingham [21], United Kingdom Prospective Diabetes Study (UKPDS) [22], Systematic Coronary Risk Evaluation (SCORE) project [23], WHO risk chart [24], NHS Heart [25] and ASCVD [26,27] were used to calculate summary estimates of CHD, Fatal CHD, Stroke, Fatal Stroke, Myocardial Infarction, CVD death, Blindness, Renal failure, Amputation, Ulcer, heart age and life expectancy. The variables used in the calculations for each of the risk engines, the exact method of calculation and related assumptions are summarised in Table 1. Appendix 1 summarises the event definitions used in each of the risk engines.

The risks for each individual were calculated using all six engines. However, such calculated risk was expectedly influenced by the original presumptions of the risk engine and several non-modifiable factors like age, gender and ethnicity. To negate the influence of non-modifiable individual-related factors like age, sex, and ethnicity, we also calculated the risk ratio (RR) [ratio of absolute risk for subject: low absolute risk level (LARL) for the subject]. *LARL (Low Absolute Risk Level)* was defined for men as the 10-year risk for a person of the same age, BP < 120/80 mmHg, TC 160–199 mg/dl, HDL ≥45 mg/dl, non-smoker and with no diabetes, and for women as the 10-year risk for total CHD endpoints for a person of the same age, BP < 120/80 mmHg, TC 160–199 mg/dl, HDL ≥55 mg/dl, non-smoker and with no diabetes. This RR provides an index of risk of the individuals compared to that of a person of the same age and gender but with no diabetes or risk factor. To further understand the mitigability of the risk through appropriate interventions a comparison was also made with Low Risk Level (LRL) and Risk at Target Level (RTL). *LRL (low Risk Level)* was defined as the risk of a person with same gender and duration of diabetes but with serum TC 4.2 mmol/l, SBP 120 mmHg, HbA1c 6.0 %, not smoking and HDL-cholesterol 1.2 mmol/l for men and 1.4 mmol/l for women. This RR provides an index of risk of the individuals compared that of a person of same age and gender with same duration of diabetes and "perfect" clinical parameters or risk factor. *RTL (Risk at Target Level)* was defined as the risk of a person with same gender and duration of diabetes but with a SBP 130 mm Hg, HbA1c 7·0 %, not smoking, HDL-cholesterol 1.04 mmol/l for men and 1.3 mmol/l for women and a non-HDL-cholesterol 3.4 mmol/l in accordance with ADA recommended targets [3]. This risk ratio provides an index of risk of the individuals compared to that of a person of the same age and gender with the same duration of diabetes and "reasonable" clinical parameters or risk factors. This exercise intentionally compares the risk of the individuals with that at baseline(assumed). In effect, it provides an index of the role played by modifiable risk factors (HbA1c, Lipids, BP, smoking) while negating the impact of non-modifiable factors (age, gender, duration of disease).

The Framingham, UKPDS, WHO risk chart, NHS Heart, and ASCVD equations/scores allow for the incorporation of the diabetes status into the calculations. UKPDS is the only model specifically accounting for the duration of diabetes and the current diabetes control (HbA1c levels). The SCORE project does not directly calculate risk for diabetes patients, but the authors have suggested that the calculated cardiovascular risk be multiplied by 2 for men and 4 for women for diabetes patients. The estimates provided are based on the same supposition and use the TC-based equations. For UKPDS calculations, it was presumed that none of the subjects had atrial fibrillation.

2.3. Biochemical analysis

A total of 5 ml of blood was collected from each participant. This is a standard volume that provides sufficient sample for multiple tests while ensuring participant safety.

- **Sample Storage and Processing:** The blood sample for HbA1c testing was stored at a temperature of 4 °C. This is a standard practice to preserve the integrity of the sample until processing, which was done within 48 h to prevent degradation. The remaining blood samples were centrifuged at a force of 1207 g, a process that

Table 1
Methodology for calculation of Cardiovascular Risk using the Risk Engines.

Variables Used for calculation	Framingham	UKPDS	SCORE	WHO	NHS Heart	ASCVD
Age	✓	✓	✓	✓	✓	✓
Gender	✓	✓	✓	✓	✓	✓
Height					✓	
Weight					✓	
Diabetes	✓		✓	✓	✓	✓
Duration of Diabetes		✓				
Smoking	✓	✓	✓	✓	✓	✓
Systolic Blood Pressure	✓	✓	✓	✓	✓	✓
Ethnicity (Asian/Indian)		✓				✓
Family Cardiac History					✓	
HbA1c		✓				
Total Cholesterol	✓	✓	✓	✓	✓	✓
HDL-Cholesterol	✓	✓			✓	✓
Antihypertensives	✓				✓	✓
Pre-existing events/Diagnosed Disease^		✓			✓	
Atrial fibrillation		◯			◯	
PVD		◯				
Hb, TLC, e-GFR		◯				
Source of Method Used for Calculation	Risk Chart [21]	UKPDS Outcome Model 2.2 [39]	Equation [23]	Risk Chart [24]	Official Online Calculator [25]	Official Online Calculator [27]

✓ Available from the community survey and used as per data available.
◯ Not Available from the community Survey and assumed to be normal for the purpose of calculation (AF- Absent; PVD-Absent; Hb-13 g/dl; e-GFR-85 ml/min/1.73 m^2; WBC-7.5 *10^9).
^Pre-existing events/Diagnosed Disease includes IHD, Heart Failure, Amputation, Blindness, Renal failure, Stroke, MI and Ulcer for UKPDS and Previous Diagnosis with Chronic Kidney Disease, Rheumatoid Arthritis for NHS heart.

separates the blood components, allowing for the extraction of serum/plasma.

- **Serum/Plasma Handling:** The separated serum/plasma was either immediately processed for biochemical analysis or stored at −70 °C. This ultra-low temperature storage prevents enzymatic reactions or microbial growth that could alter the sample.
- **Biochemical Analysis:** Lipid profile and blood glucose estimation were done using a Hitachi 902 analyzer. HbA1c was tested by low-pressure liquid chromatography (Biorad Diastat analyzer; DCCT aligned).
- **Quality Control Measures:** To ensure the accuracy and reliability of the results, 5 % of the samples were randomly selected and reanalyzed. The coefficients of variation (a measure of relative variability) for HbA1c, serum cholesterol, and fasting blood glucose were within acceptable ranges (5 %, 3 %, and 2.5 % respectively), indicating consistency in the measurements.

2.4. Sample size considerations

The community survey aimed to estimate the prevalence of poor glycemic control in T2D patients in Delhi, with an acceptable relative error of 10 % and an alpha error of 0.05, using a cluster random sampling design and 80 % power. Based on earlier data [28] and a population estimate of 1,122,000 known T2D patients in Delhi [29], it was determined that 768 subjects would be adequate to achieve the desired precision. A design effect of 2.0 was assumed due to the lack of information within or between cluster variations. To achieve the required sample size and the assumed design effect, at least 30 subjects were recruited from each of the 30 clusters. For the risk projections all available data points were used for the analysis without the need for additional sample size calculations.

2.5. Data analysis

The data analysis was conducted using complex sample procedures

Table 2
Socio-demographic characteristics: Excluded or refused blood sampling(Mean/%age(95%CI).

Subjects Excluded from the survey(n = 87 of 930)[a]				
Characteristics	Overall n = 889	Included n = 843	Excluded n = 46	p-value
Age(yrs)	55.2(52.3–54.1)	53.1(52.1–54.0)	55.1(50.1–60.1)	0.439
M:F (%)	49.9(45.3–54.4)	50.2(45.8–54.5)	45.5(27.3–65.1)	0.628
Mean Duration of Diabetes(yrs)	7.2(6.8–7.6)	7.1(6.7–7.6)	8.4(6.2–10.6)	0.289
Low Income Group Status(%)	52.7(30.8–73.7)	52.6(30.1–74.0)	55.3(25.7–81.6)	0.858
Middle Income Group Status(%)	32.3(14.6–57.2)	32.0(14.4–57.0)	36.6(11.1–72.7)	0.737
High Income Group Status(%)	15.0(5.1–36.7)	15.4(5.0–38.6)	8.1(2.0–27.5)	0.456
Subjects who refused blood sampling(n=43 of 843)				
Characteristics	**Overall n=843**	**Included n=800**	**Refused n=43**	**p-value**
Age(yrs)	53.1 (52.1–54.0)	52.8 (51.9–53.7)	57.0 (52.4–61.6)	0.067
M:F (%)	50.2 (45.8–54.5)	49.2 (44.3–54.1)	66.1 (51.6–78.1)	**0.036**
Mean Duration of Diabetes(yrs)	7.2 (6.7–7.6)	7.2 (6.8–7.7)	5.9 (2.6–9.2)	0.435
Low Income Group Status(%)	52.6 (30.1–74.0)	54.1 (31.2–75.4)	27.8 (7.8–63.8)	0.074
Middle Income Group Status(%)	32.0 (14.4–57.0)	32.6 (14.6–57.8)	22.7 (5.6–59.0)	0.424
High Income Group Status(%)	15.4 (5.0–38.6)	13.3 (4.3–34.7)	49.5 (13.5–86.0)	0.071

[a] Forty one patients refused permission to record any of their data.

Table 3
Sociodemographic profile of the population (n = 843)[a].

Characteristic	Overall		Women		Men		p- value
	%	95 % CI	%	95 % CI	%	95 % CI	
Place of Origin							
Migrated from other states in India[b]	58.3	49.6–66.6	66.3	56.5–74.9	50.4	40.8–59.8	**<0.001**
Migrated from other Countries	0.9	0.4–2.0	1.3	0.5–3.2	0.5	0.1–2.5	
Residing in Delhi	40.8	32.6–49.5	32.4	24.4–41.6	49.1	39.4–58.9	
Education level							
Illiterate	17.3	11.3–25.6	27.1	18.3–38.1	7.6	4.0–13.4	**<0.001**
Primary School Certificate	15.0	12.6–17.9	18.1	14.7–22.1	12.0	8.4–16.9	
Middle School Certificate	14.3	11.8–17.3	12.2	8.8–16.7	16.5	13.3–20.3	
High School Certificate	24.5	20.7–28.7	17.6	12.9–23.5	31.4	27.3–35.8	
Intermediate Certificate	9.0	5.9–13.6	8.3	4.9–13.8	9.8	6.0–15.5	
Graduate	14.4	9.7–20.9	10.1	6.0–16.6	18.6	12.1–27.5	
Postgraduate or Professional	5.4	3.1–9.2	6.6	3.1–13.2	4.2	2.3–7.7	
Monthly income (INR)[c]							
>41,430	23.0	14.7–34.3	22.0	13.9–33.0	24.1	14.2–38.0	0.982
20,715–41,429	20.5	15.9–26.1	20.7	15.2–27.6	20.4	15.2–26.8	
10,357–20,714	30.2	24.1–37.1	31.1	23.7–39.7	29.3	23.0–36.6	
<10,356	26.2	20.0–33.4	26.2	18.1–36.3	26.1	20.4–32.9	
Employment status							
Employed	57.2	51.9–62.4	18.8	12.5–27.2	95.5	91.6–97.6	**<0.001**
Unemployed	42.8	37.6–48.1	81.2	72.8–87.5	4.5	2.4–8.4	
Medical benefits[d]	44.6	34.0–55.7	39.8	29.1–51.5	49.4	37.5–61.5	**0.031**
Healthcare provided at							
Private clinics or nursing homes/Local doctor clinic	32.1	26.1–38.8	34.3	26.1–43.5	30.0	23.1–38.0	**0.026**
Hospital							
Government	33.1	25.8–41.2	36.9	29.8–44.7	29.2	21.0–39.0	
Private	5.6	4.0–7.7	6.6	4.3–9.8	4.6	2.6–8.1	
Alternative medicine[e]	3.2	1.9–5.1	2.7	1.1–6.5	3.7	2.2–6.2	
No doctor/Self-medication	26.0	19.6–33.7	19.6	13.4–27.6	32.5	24.1–42.1	
Qualification of PCP (showing to doctor n = 621; Self-medication n = 222)							
Endocrinologist[f]	8.6	5.9–12.4	7.3	3.9–13.3	9.9	6.5–14.7	**<0.001**
General Physician[g]	56.4	51.3–61.4	64.7	59.1–70.0	48.2	41.0–55.4	
Specialist physician[h]	2.4	1.2–4.6	2.0	0.8–4.8	2.8	1.2–6.3	
Qualification not known[i]	6.6	3.5–12.0	6.4	3.2–12.3	6.7	3.4–12.9	
Smoking							
Current	15.8	11.8–20.7	4.1	1.4–11.6	27.3	21.5–34.0	**<0.001**
Former	7.8	5.6–10.9	0.9	0.3–2.9	14.6	10.5–20.1	
Never	76.4	70.4–81.6	94.9	87.4–98.1	58.1	50.7–65.2	
Alcohol User							
Current	25.1	21.7–28.8	2.4	0.9–6.6	47.6	42.4–52.8	**<0.001**
Former	9.9	7.4–13.1	1.7	0.7–4.1	18.0	14.1–22.7	
Never	65.0	60.7–69.1	95.8	91.7–98.0	34.4	29.9–39.2	
Frequency per month[j]	11.9	10.0–13.8	2.1	0.5–3.7	12.4	10.5–14.3	
Family Type- nuclear	46.5	40.2–52.9	42.6	35.6–50.0	50.3	42.9–57.6	**0.037**
Mean Number of family members	6.0	5.3–6.6	6.0	5.2–6.8	6.0	5.3–6.4	0.664

PCP: Primary Care Provider.
MBBS: Bachelor of Medicine and Bachelor of Surgery.
MD: Doctor of Medicine.
DM: Doctorate of Medicine.
[a] All data presented have been adjusted for the two-stage cluster sampling design of the survey.
[b] Migrated to Delhi from elsewhere in India.
[c] Gross family monthly income ((Indian Rupees, INR); including that of husband and wife); monthly income of INR 41,430 corresponds to ~USD 505 per month.
[d] Individuals receiving any medical benefit (government insurance schemes, private medical insurance, or medical reimbursement).
[e] Includes practitioners of homeopathy, ayurvedic medicine, naturopathy, and other alternative systems.
[f] Reported qualification of PCP is DM (Endocrinology).
[g] Reported qualification of PCP is MBBS.
[h] MBBS, MD in any specialty, or DM in a specialty other than endocrinology.
[i] Qualification of PCP is not known.
[j] Only for patients currently drinking alcohol (n = 190).

in SPSS v 25.0. The following steps were taken.

- **Data Preparation:** The raw data was first cleaned and prepared for analysis. This involved handling missing data, and outliers, and ensuring the data met the assumptions of the statistical tests to be used.
- **Weighting:** Given the complex sampling design, it was necessary to apply weights to the data. These weights were calculated based on the inverse probability of selection for each observation (participant), taking into account stratification and clustering in the sample design. This is done using the sampling file available from the survey design steps. This file is used for each of the analytic commands used below.
- **Descriptive Statistics:** Descriptive statistics were calculated for all variables of interest, including measures of central tendency (mean, median; CSDESCRIPTIVES) and dispersion (standard deviation, interquartile range). These statistics were calculated separately for men and women and by care providers, and differences were estimated between categories (CSGLM).

3. Results

3.1. Demographic profile

A total of 11,490 houses (289–1030 per cluster) were screened. We identified 1640 known diabetes patients, of which 238 failed to meet the inclusion criteria (39 had diabetes for less than one year; 28 had never had any blood glucose estimation; 171 were outside the specified age criteria), and 87 were excluded. In the case of 472 patients, the research team was denied access by relatives or self or the subject refused consent after discussion. Hence, 843 T2D subjects were administered the questionnaire. Out of 843 recruited subjects, 43 declined to give blood samples after initial recruitment; therefore, laboratory data is available for 800 subjects. The subjects recruited (n = 843) were comparable to those who refused consent for age, duration since diagnosis, socio-economic status, and gender ($p > 0.05$; Table 2). Also, the subjects who refused consent specifically for blood sampling (n = 43) were mostly comparable to those who consented (n = 800) for all baseline characteristics ($p > 0.05$; Table 2; a higher proportion of men refused). Table 3 depicts the sociodemographic profile of the respondents/patients. The mean age of the respondents was 53.0 years among both genders. More than 58 % of the population migrated from other states of India to Delhi, and only 40 % of the population belonged to Delhi. 24.5 % of respondents had high school or above education. The majority of the population had a monthly income of < INR 20,000 per month. Only 8.6 % of patients consulted with an endocrinologist, while more than 55 % of patients consulted with a general physician for diabetes. More than one-fourth of the men were current smokers (15.8 %) while 25.1 % were currently consuming alcohol.

3.2. Cardiovascular morbidity, risk profile, and management

The existing lifetime morbidity, reported management and the current cardiovascular risk profile of the subjects are presented in Table 4. The mean age at onset of diabetes was 45.9 (44.9–46.9) years, with a mean diabetes duration of 7.1 (6.7–7.5) years. It is noteworthy that 74.6 % of the subjects had a Body Mass Index (BMI) > 25 kg/m^2, 84.6 % had a waist circumference beyond suggested cut-offs for Indians [5], 61.8 % were hypertensive, 81.5% were dyslipidemic and 53.3 % had poor glycaemic control (HbA1c>8 %; 64 mmol/mol). 8.4 % had already had a myocardial infarction, 61.8% of subjects had a current SBP ≥ 140 mmHg or a DBP ≥ 90 mmHg, and 1.2 % had suffered from a stroke. However, only 9.3 % (of 97.3 % requiring) [3] were taking aspirin, 16 % were on lipid-lowering drugs, while 98.5 % would have required the same as per the current ADA recommendations [3]. 39.9 % of patients reported hypertension, out of which 58.2 % were taking medication for high BP. 16.8 % were not aware of their hypertension but taking medicine for it.

3.3. Ten-year cardiovascular risk projection

To obtain a composite picture of the cardiovascular risk of these diabetes patients, various cardiovascular risk projection equations were used. The results are depicted in Table 5. Although not strictly comparable (due to differences in cardiovascular endpoints and the baseline variables studied), all the risk engines estimate the overall 10-year CHD risk to be between 14.6 and 16.1 % and that of stroke 5.0 % (4.5–5.4), fatal CVD 2.5 %. The average RR estimates for CHD using the Framingham and UKPDS risk equations (Table 5) varied from 2.5 to 3.0 for the overall population, 2.9 to 3.1 for men, and 2.1 to 3.0 for women.

The mean absolute risk, LRL and RTL for each age quartile and gender using the UKPDS engine are presented in Fig. 1. As depicted, the mean actual risk was 1.49–2.03 times the RTL and 1.98 to 2.95 times the LRL. The risk was highest for those taking Alternative Medicines or on Self-care and lowest for those on institutional care.

The calculated NHS mean Heart Age was 68.1 years (95 % CI (66.8–69·4)), 66.8 years; 95 % CI(65.8–67.9) for women and 69.4 years; 95 % CI (67.2–71.6) for men. The LARL mean heart age was 51.9 years (95 % CI 50.9–52.8) corresponding to an age gap of ~16 years. The mean life expectancy is 75.3 years (95 % CI (74.8–75.8)), 77.3 years; 95 % CI(76.8–77.8) and 73.2 years; 95 % CI(72.8–73.7) for overall, women and men respectively. The life expectancy at LARL was 84.0 years (95 % CI 83.7–84.2) corresponding to ~9 years loss in expectancy [20].

4. Discussion

4.1. Interpretation of key findings

The present study shows that diabetes population of Delhi (low-, middle- and high-income group) has an 1.5 to 3.0 times elevated decadal cardiovascular risk leading corresponding to a loss of ~9 years in life expectancy. There is high prevalence of pre-existing cardiovascular morbidity. The use of screening investigations (ECG and exercise testing) and cardioprotective measures such as aspirin, lipid-lowering drugs and antihypertensive drugs could be better compared with standard practice recommendations [[3–5]; >95 % of the study subjects would have required]. Much of this risk is mitigable, considering the much lower risk at target levels.

4.2. Strengths and limitations

The research is unique in providing comprehensive decadal estimates of a variety of macrovascular and microvascular risks amongst diabetes patients of Delhi using epidemiologically robust community survey data. The study calculates cardiovascular risk by using direct test reports/centralized laboratory estimates, BP measurements, standardized event definitions, and established risk scores, enhancing the reliability of the projections. Our work uses an approach (pooled cohort equations) endorsed by the American College of cardiology, American Diabetes Association, and the U.S. Preventive Services Task [30]. We use a variety of risk prediction equations in international use (including those accounting for South Asian ethnicity) to provide a comprehensive overview of the risk picture to the reader. Uniquely, the work puts this risk in the context of the poor quality of diabetes care (our previously published paper) [7] and the poor use of cardioprotective interventions highlighting the eminently mitigable nature of the risk and the urgency of community-based interventions.

The study was limited to adults aged 35–65 years to reduce the impact of aging on patient outcomes, though this could limit generalizability. Although the scores are validated elsewhere in a variety of populations [31,32] the study is constrained by the lack of validation of the cardiovascular risk scores used for 10-year risk projection in the Indian population (the Framingham risk score is based on data from Whites, and UKPDS for British populations (includes Indians living in the UK), whereas SCORE was developed for European populations). Therefore, the absolute values of risk serve as crude composite indices of the various factors affecting cardiovascular risk rather than as accurate estimates of absolute risk. However, RR estimates are more likely to be valid, as they negate the influence of factors such as ethnicity and socio-demographic profile. Furthermore, estimates based on the UKPDS equations are likely to be more accurate, as they specifically incorporate duration of diabetes, glycaemic control and ethnicity. They also provide the widest array of morbidity projections. The projections are limited by the absence of reliable medical documentation, electronic medical records or disease registries. The study relies on self-reported clinical history, which can increase a variety of biases like selective recall, time-dependent recall, differential recall etc. Direct information regarding presence of atrial fibrillation, e-GFR and peripheral vascular disease, is not collected which may lead to an underestimation of the risk of stroke/CAD by UKPDS. The exclusion of subjects with chronic diseases could possibly underestimate cardiovascular risk.

Table 4
Cardiovascular risk factor profile, morbidity, and management in diabetes patients.[a].

Characteristic	Overall *(n=843)*		Women *(n=438)*		Men *(n=405)*		p-value
	%/Mean	95 % CI	%/Mean	95 % CI	%/Mean	95 % CI	
Risk factor profile							
Age (years; mean)	53.0	52.1–54.0	53.0	52.0–54.1	53.0	51.7–54.4	0.968
Sex (%)	–	–	49.8	45.5–54.2	50.1	45.8–54.5	–
Age at diagnosis (year; mean)	45.9	44.9–46.9	46.0	45.0–47.0	45.8	44.2–47.3	0.759
Duration since diagnosis (years; mean)	7.1	6.7–7.5	7.0	6.4–7.7	7.2	6.4–8.1	0.732
Body mass index							
Mean (kg/m^2)	28.2	27.8–28.6	29.5	28.8–30.2	26.9	26.4–27.3	**<0.001**
>25 kg/m^2(%)	74.6	70.7–78.1	81.1	74.7–86.2	68.1	61.8–73.8	**0.008**
Waist circumference							
Mean (cm)	100.7	99.6–101.7	100.5	98.9–102.2	100.8	99.5–102.0	0.773
>Cut-off (%)[b]	84.6	81.1–87.6	82.4	77.2–86.5	86.9	81.3–91.0	0.207
HbA1c							
Mean (%)	8.8	8.5–9.2	8.7	8.3–9.1	9.0	8.6–9.3	0.330
Mean (mmol/mol)	73	69–77	72	67–76	75	70–78	0.330
> 8 % (>64 mmol/mol)	53.3	47.8–58.7	48.9	42–55.8	57.6	49.9–65.0	**0.007**
Blood Pressure							
Systolic Blood Pressure (mean; mmHg)	138.8	136.5–141.1	138.0	135.2–140.9	139.6	136.8–142.5	0.353
Diastolic Blood Pressure (mean; mmHg)	90.2	88.4–92.0	88.9	87.0–90.7	91.5	89.2–93.8	**0.010**
Hypertensive[c]	61.8	56.2–67.2	62.3	55.8–68.3	61.4	52.9–69.3	0.864
Lipid Profile							
Mean Total cholesterol (TC; mmol/l)	4.8	4.7–4.9	4.8	4.7–4.9	4.7	4.6–4.9	0.512
Mean HDL-cholesterol (mmol/l)	1.1	1.1–1.1	1.2	1.1–1.2	1.1	1.0–1.1	**0.001**
Mean LDL-cholesterol (mmol/l)	2.9	2.8–3.0	2.9	2.8–3.0	2.9	2.8–3.1	0.886
Mean Triglycerides (mmol/l)	2.1	2.0–2.2	2.0	1.8–2.1	2.3	2.0–2.5	**0.043**
Mean TC: HDL ratio	4.3	4.2–4.4	4.1	3.9–4.3	4.5	4.3–4.7	**0.003**
Dyslipidaemia (%)[d]	81.5	75.9–86.0	84.0	79.2–87.9	79.0	70.6–85.4	0.080
Mean Fasting blood glucose (mmol/l)	9.8	9.2–10.3	9.6	9.0–10.2	10.0	9.2–10.8	0.408
Metabolic syndrome (%)[e]	85.9	82.3–88.8	89.1	84.3–92.6	82.7	78.0–86.5	**0.014**
Family History							
Diabetes	64.4	57.9–70.3	61.1	50.4–70.8	67.6	61.7–73.1	0.240
Coronary Artery Disease	20.2	17.1–23.6	23.2	18.4–28.7	17.2	14.1–20.8	**0.040**
Stroke	4.0	2.5–6.4	2.7	1.3–5.2	5.4	3.0–9.5	0.091
Self-reported morbidity[f](%)							
CAD	7.3	5.4–9.9	5.7	3.5–9.1	8.9	6.0–13.1	0.151
Hypertension	39.9	35.9–44.0	45.2	40.1–50.3	34.7	29.1–40.7	**0.007**
Stroke	1.2	0.5–2.8	1.6	0.6–4.2	0.9	0.3–2.7	0.353
Foot amputation	0.4	0.1–1.4	0.3	0.0–2.2	0.4	0.1–2.5	0.822
Investigations and management (%)							
ECG[g]	15.4	11.9–19.7	14.0	10.6–18.3	16.7	12.3–22.3	0.183
Exercise testing[h]	1.8	0.9–3.8	1.0	0.3–2.6	2.7	1.1–6.5	0.115
Aspirin therapy	9.3	7.2–12.0	7.8	4.8–12.2	10.8	7.8–14.7	0.558
Requiring aspirin therapy[i]	97.3	95.7–98.3	96.6	92.3–98.5	97.9	95.7–99.0	0.459
Lipid Lowering therapy	16.0	13.3–19.1	15.0	12.4–18.2	16.6	12.9–21.1	0.380
Requiring lipid lowering[j]	98.5	96.5–99.4	98.1	93.4–99.4	99.0	97.0–99.7	0.446

SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HDL: High-density lipoprotein; LDL: Low-density lipoprotein.

[a] All data presented have been adjusted for the two-stage cluster sampling design of the survey.

[b] Suggested action level II cut-offs for Indian adults are >80 cm in women and >90 cm in men [5].

[c] Current blood pressure >140/90 mmHg or known hypertensive.

[d] Low Density Lipoprotein >3.38 mmol/l or High Density Lipoprotein <1.04 mmol/l in men or HDL <1.30 mmol/l in women or triglycerides >1.65 mmol/l.

[e] Defined in accordance with the International Diabetes Federation consensus definition [4].

[f] The reported prevalence is that of only self-reported CHD without any verification of records.

[g] Electrocardiogram (ECG) required in almost all diabetes patients as baseline work-up as per the American Diabetes Association (ADA) [3] and Indian Council of Medical Research [5] guidelines.

[h] Required in all study subjects as exercise test now recommended for all diabetes patients >35 years of age [3].

[i] Based on ADA recommendations to administer aspirin to all people with diabetes >40 years of age, or those 30–40 years who smoke or have hypertension, or a family history of Coronary Artery Disease(CAD) [3]. Similarly, the International Diabetes Federation [4] recommends aspirin in all subjects known to have CVD or are at high risk and Indian Council Medical Research [5] recommends aspirin use in all diabetes patients with one or more associated risk factors such as hypertension, smoking, or dyslipidemia.

[j] Based on ADA recommendations to administer lipid-lowering drugs to all people with diabetes >40 years of age, or those <40 years with any other risk factor for CAD or overt CAD [3]. Similarly, the International Diabetes Federation [4] recommends the use of statins in all subjects >40 years old or with declared CVD.

4.3. Comparison with previous studies

Several studies across the world [33,34] and in India [16] have previously attempted use of risk engines for cardiovascular risk projection including our own work [35]. However, those attempting the same in known diabetes patients in India are few [17,18]. The results of the current work are grossly consonant to those obtained recently by Bansal et al. [18] This study conducted on newly diagnosed diabetes patients in a public hospital in Chandigarh reports a mean FRS risk of 15.1 % and a UKPDS risk of 13.4 %. The FRS projections are our study were similar (14.6 %) while the UKPDS risk was higher(16.1 %) probably due to the restriction of the Chandigarh study to newly diagnosed patients while our patients had a mean duration since diagnosis of 7.1 years. It is noteworthy that despite being newly diagnosed, the subjects in the both studies had a mean HbA1c of 8.8 % (73 mmol/mol). A similar study from Western India [17] reported lower risk profile and risk scores using the

Table 5
Ten-year cardiovascular risk projection (n = 800).

Risk Engines	Overall		Women		Men		p-value
	Absolute risk (95 % CI)	Risk Ratio (95 % CI)	Absolute risk (95 % CI)	Risk Ratio (95 % CI)	Absolute risk (95 % CI)	Risk Ratio (95 % CI)	
Based on Framingham Score[a] (%)							
10 Years CHD Risk	14.6 (13.7–15.5)	2.5 (2.3–2.7)	12.9 (12.1–13.7)	2.1 (2.0–2.3)	16.3 (14.7–17.9)	2.9 (2.6–3.2)	**<0.001**
Based on UKPDS Model 2.0[b](%)							
CHD	16.0 (14.9–17.1)	3.0 (2.7–3.3)	10.6 (9.7–11.6)	3.0 (2.7–3.3)	21.5 (19.8–23.2)	3.1 (2.6–3.5)	**<0.001**
Stroke	5.0 (4.5–5.4)	2.6 (2.1–3.0)	3.8 (3.5–4.1)	2.0 (1.7–2.2)	6.2 (5.4–6.9)	3.2 (2.3–4.1)	**<0.001**
Based on UKPDS Outcome Model 2.1[b](%)							
CHD	16.1 (15.1–17.0)	1.5 (1.5–1.6)	10.5 (9.9–11.2)	1.4 (1.3–1.5)	21.8 (20.3–23.3)	1.6 (1.5–1.8)	**<0.001**
Myocardial Infarction	10.3 (9.5–11.1)	1.8 (1.7–1.9)	6.1 (5.7–6.6)	1.5 (1.4–1.7)	14.7 (13.3–16.1)	2.1 (1.9–2.3)	**<0.001**
Stroke	3.7 (3.4–4.1)	2.4 (2.2–2.7)	2.9 (2.6–3.2)	2.4 (2.0–2.7)	4.6 (3.9–5.2)	2.5 (2.2–2.8)	**<0.001**
CVD Death	5.0 (4.5–5.5)	1.9 (1.8–2.1)	3.1 (2.8–3.4)	1.7 (1.5–1.9)	6.9 (6.0–7.8)	2.2 (2.0–2.4)	**<0.001**
Blindness	2.7 (2.4–2.9)	2.2 (2.0–2.5)	2.6 (2.4–2.9)	2.3 (2.0–2.6)	2.7 (2.4–3.0)	2.2 (2.0–2.4)	0.611
Renal Failure	0.2 (0.2–0.3)	1.5 (1.0–2.1)	0.1 (0.1–0.2)	1.6 (0.7–2.5)	0.4 (0.3–0.5)	1.5 (1.2–1.8)	**<0.001**
Amputation	2.0 (1.7–2.4)	3.8 (3.3–4.2)	1.3 (1.0–1.6)	3.8 (2.9–4.7)	2.8 (2.1–3.5)	3.7 (3.4–4.0)	**0.001**
Ulcer	1.1 (1.0–1.2)	1.7 (1.5–1.9)	0.6 (0.4–0.7)	1.5 (1.2–1.9)	1.6 (1.4–1.8)	1.9 (1.6–2.1)	**<0.001**
Based on SCORE Project[c](%)							
Overall Fatal CVD	5.7 (5.1–6.2)	3.6 (3.4–3.9)	4.6 (4.2–5.0)	4.7 (4.4–5.2)	6.8 (5.8–7.7)	2.5 (2.2–2.8)	**<0.001**
Fatal Coronary HD	4.3 (3.8–4.7)	3.7 (3.4–4.0)	2.9 (2.6–3.2)	4.7 (4.4–5.1)	5.7 (4.9–6.5)	2.6 (2.3–2.9)	**<0.001**
Fatal non-coronary CVD	1.4 (1.2–1.5)	3.3 (3.0–3.6)	1.6 (1.5–1.8)	4.7 (4.4–5.2)	1.1 (0.9–1.2)	1.9 (1.6–2.1)	**<0.001**
Based on WHO Risk Charts[d](%)							
CVD Risk level	10.7 (10.2–11.3)	3.1 (2.9–3.4)	9.3 (8.9–9.8)	2.8 (2.7–3.0)	12.2 (11.3–13.1)	3.5 (3.1–3.9)	**<0.001**
Based on ASCVD Risk Estimator[e](%)							
10-year ASCVD Risk	9.6 (8.8–10.4)	4.6 (4.1–5.1)	5.3 (4.9–5.7)	4.6(3.8–5.3)	14.0(12.7–15.4)	4.7(4.2–5.2)	**<0.001**
Lifetime ASCVD Risk	51.0 (49.9–52.2)-	1.6 (1.5–1.6)	43.1 (42.4–43.9)	1.6(1.5–1.6)	59.2(57.7–60.6)	1.6(1.6–1.7)	**<0.001**

CHD, Coronary Heart Disease; CVD, Cardiovascular Disease.

[a] Framingham score [16] predicts 10-year CHD (Coronary Heart Disease) risk (Determine the number of points a patient receives for each risk factor-age, LDL-C, Cholesterol, HDL-C, Blood Pressure, Diabetes, smoker and calculates CHD 10-year risk).

[b] United Kingdom Prospective Diabetes Study [17] risk engine calculates the 10-year risk for CHD, Fatal CHD, Stroke and Fatal Stroke UKPDS outcome model 2.1 is a computerised simulation tool designed to estimate Life Expectancy, Quality Adjusted Life Expectancy and the cumulative costs of complications in people with type 2 diabetes mellitus.

[c] Systematic Coronary Risk Evaluation [18] project predicts the 10- year of fatal cardiovascular disease.

[d] WHO [19] cardiovascular disease risk laboratory-based charts estimate CVD (Cardiovascular Disease) incidence.

[e] This Risk Estimator enables health care providers and patients to estimate 10-year and lifetime risks for Atherosclerotic Cardiovascular Disease (ASCVD) [21], defined as coronary death or nonfatal myocardial infarction, or fatal or nonfatal stroke, based on the Pooled Cohort Equations and lifetime risk prediction tools.

QRISK-3 (15.1 % vs 16.1% using UKPDS in our study). In comparison with our own earlier work in Delhi, the risk profile of the subjects is worse with a higher mean HbA1c(8.8 % vs 7.8 %; 73 vs 62 mmol/mol) and poor quality of care [7] while certain aspects like the use of lipid-lowering (3.2 % vs 16.0 %) and anti-hypertensive medications (11.6 % vs 30.0 %) were better. The risk of CHD was higher in the current study(16.0 % vs 13.8%) while that of stroke was comparable (5.0 % vs 5.7 %; mean SBP in the current study was lower possibly due to wider anti-hypertensive use).

4.4. Clinical implications

As one is aware, high-quality diabetes care includes dimensions like diabetes self-management education, Lifestyle modification counselling, Self-monitoring of Blood Glucose, Smoking cessation counselling, appropriate use of medications like oral hypoglycemics, insulin, lipid-lowering medications and anti-hypertensives etc, periodic biochemical estimations and regular screening for early detection of complications. In our related previous publication(ref), we focused on the quality of care delivered, whereas in this current report, we project its implications. Both works emphasize the importance of providing high-quality diabetes care to every patient in every instance by every care provider. This is crucial to improve patient outcomes and reduce healthcare costs associated with diabetes-related complications.

4.5. Public health implications

The poor cardiovascular profile of known diabetes patients documented by our study burdens the population with a high ten-year risk of having CHD (~800,000 million new cases projected to Delhi's ~5 million diabetes patients; based on UKPDS Risk Engine) and stroke (~185,000) with an estimated 250,000 fatalities. These higher

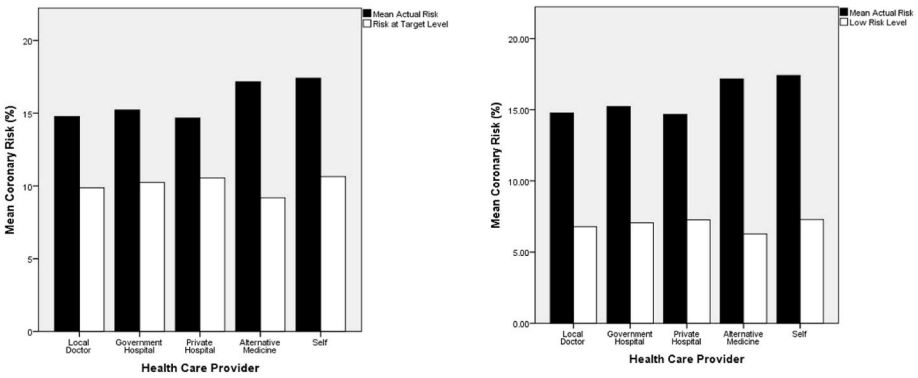

Fig. 1. Mean coronary heart disease risk of diabetes patients compared with Low-Risk Levels and Risk at Target Levels. The figure is a stacked bar chart depicting the risk on basis of health care providers like local doctors, Private and Government hospitals, alternative medicines and selfcare. Clinics, nursing home and trust hospitals (<25 beds) included in the Local Doctors where consultation was charged; all Government dispensaries, Moholla clinics and government hospital (no consultation charged) were covered into Government Hospitals, more than 25 bedded hospitals and where consultations were charged fall into the Private Hospital category; Ayurvedic/Homeopathy & Naturopathy comes under Alternative Medicines; and the category of Self is defined as patients was not consulted with any health care providers from past 1 year or more and taking medicines by their own. Mean actual absolute risk as the black series and the low-risk level (LRL) or risks at target levels (RTL) as the white series. LRL, Risk of a person with same gender and duration of diabetes but with total serum cholesterol 4.2 mmol/l, systolic blood pressure (SBP) 120 mmHg, HbA1c 6.0 %, not smoking and high-density lipoprotein (HDL)-cholesterol 1.17 mmol/l for men and 1.43 mmol/l for women; RTL, risk of a person with same gender and duration of diabetes but with SBP 130 mmHg, HbA1c 7.0 %, not smoking, HDL-cholesterol 1.04 mmol/l for men and 1.30 mmol/l for women and a non-HDL-cholesterol 3.38 mmol/l in accordance with American Diabetes Association recommended targets.

projections (than in DEDICOM-I) are due to a combination of the increase in the population of Delhi, the rise in the prevalence of diabetes and the higher estimated risks. Importantly, these co-morbidities are eminently mitigable with evidence that above an HbA1c of 7 %, every 1 % higher level was associated with a 38 % higher risk of a macrovascular event, a 40 % higher risk of a microvascular event and a 38 % higher risk of death [36]. Similarly, every 10 mm Hg systolic blood pressure reduction reduced the risk of major cardiovascular events by 20 % (relative risk [RR] 0.80, 95 % confidence interval [CI] 0.77 to 0.83), coronary heart disease by 17 % (RR 0.83, 95 % CI 0.78 to 0.88), stroke by 27 % (RR 0.73, 95 % CI 0.68 to 0.77), heart failure by 28 % (RR 0.72, 95 % CI 0.67 to 0.78), and death from all causes by 13 % (RR 0.87, 95 % CI 0.84 to 0.91) [37]. Also, aggressive management of dyslipidemia can reduce the risk of major cardiovascular events by 37 % [38].

5. Conclusions

In conclusion, the study highlights the impending impact of, and the scope for improvement in the cardiovascular risk profile of diabetes patients in Delhi, including the use of cardioprotective medications. It strengthens the case for targeting cost-effective community-based interventions/public health programs for patients, providers, and other stakeholders. The very low rates of use of lipid-lowering drugs, antihypertensive, and other medications suggest the need for understanding barriers to better care at the level of the providers and patients. Further research is required to develop risk equations specific to Indian subjects.

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Author's contribution

JN conceived the idea, developed the study design, supervised the execution of the study plan, supervised the data analysis and will act as guarantor for the paper. SR was involved with the study design, data analysis and drafting of the manuscript. SG led the data collection in the community. SG and RY executed the analysis plan and carried out the data analysis. JN and SR were involved in the finalization of the manuscript. All authors have read and approved the submitted version.

Ethical approval

The project was approved by the Institutional Ethics Committee at Sitaram Bhartia Institute of Science and Research (ref no IEC/SBISR/2015/2).

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr JITENDER NAGPAL reports financial support was provided by Indian Council of Medical Research.

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Appendix 1. Study Definitions

1. **Known diabetes for 1 year**: Patient having diabetes at least for 1 year or more and is diagnosed by Health Care Provider. Medical records were checked for confirmation.
2. **Type 1 diabetes**: Anyone having diabetes since childhood and/or dependent on insulin only.
3. **Migration**: Those who are migrated from other states to Delhi and staying in Delhi from last one generation only.
4. **Cardiovascular mortality (SCORE):** ICD-9 codes 401–414 and 426–443, instantaneous death (798.1) and death within 24 h of onset of symptoms (798.2), but excluding definitely non-atherosclerotic causes; this includes causes such as arrhythmias, cerebrovascular disease, peripheral vascular disease, aortic and other aneurysms and dissection, MI, etc.

5. **RR (*Relative Risk*)**: Ratio of absolute risk for subject: low absolute risk level (LARL) for the subject
6. ***LARL (Low Absolute Risk Level)***: Defined for men as the 10-year risk for total CHD end-points for a person of the same age, BP < 120/80 mmHg, TC 160–199 mg/dl, HDL ≥45 mg/dl, non-smoker and with no diabetes, and for women as the 10-year risk for total CHD end-points for a person of the same age, BP < 120/80 mmHg, TC 160–199 mg/dl, HDL ≥55 mg/dl, non-smoker and with no diabetes.
7. ***LRL (low Risk Level)***: Defined as the risk of a person with same gender and duration of diabetes but with serum TC 4.2 mmol/l, SBP 120 mmHg, HbA1c 6.0 %, not smoking and HDL-cholesterol 1.2 mmol/l for men and 1.4 mmol/l for women.
8. ***RTL (Risk at Target Level):*** Defined as the risk of a person with same gender and duration of diabetes but with a SBP 130 mm Hg, HbA1c 7.0 %, not smoking, HDL-cholesterol 1.04 mmol/l for men and 1.3 mmol/l for women and a non-HDL-cholesterol 3.4 mmol/l in accordance with ADA recommended targets.

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