Change in Cardiovascular Risk Factor Profile of a Rural Cohort in Thiruvananthapuram District, Kerala

Dr.T.SATHISH

Dissertation Submitted in Partial Fulfillment of the Requirement for the Award of the Degree of Master of Public Health

Achutha Menon Centre for Health Science Studies
Sree Chitra Tirunal Institute for Medical Sciences and Technology
Thiruvananthapuram 695 011, Kerala, India

Dedication

The work embodied in this dissertation is dedicated to my beloved father

His financial support made this work possible

Acknowledgement

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Last but not the least; I thank all the participants of my study for their excellent cooperation and support given.

Declaration

I hereby declare that the work embodied in this dissertation titled "Change in Cardiovascular Risk Factor Profile of a Rural Cohort in Thiruvananthapuram District, Kerala" is the result of original research and has not been submitted for any degree in any other university or institution.

Dr.T.Sathish

MPH 2009

Achutha Menon Centre for Health Science Studies,

Sree Chitra Tirunal Institute for Medical Sciences and Technology,

Thiruvananthapuram - 695 011, Kerala, India.

Dated:

Certificate - Guide

I hereby certify that the work embodied in this dissertation titled “Change in Cardiovascular Risk Factor Profile of a Rural Cohort in Thiruvananthapuram District, Kerala” is a bonafied record of original research work undertaken by Dr.T.Sathish in partial fulfillment of the requirement for the award of the Master of Public Health degree under my guidance and supervision.

Dr.Kannan Srinivasan PhD

Associate professor

Achutha Menon Centre for Health Science Studies,

Sree Chitra Tirunal Institute for Medical Sciences and Technology,

Thiruvananthapuram - 695 011, Kerala, India.

Dated:

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Dr.K.R.Thankappan M.D, MPH

Professor and Head

Achutha Menon Centre for Health Science Studies,

Sree Chitra Tirunal Institute for Medical Sciences and Technology,

Thiruvananthapuram - 695 011, Kerala, India.

Dated:

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Abstract

Background and Objectives: India is experiencing an alarming rise in the burden of cardiovascular diseases and its risk factors. There is limited evidence on the changes happening in these risk factors over a time period in the rural areas of India. This study aims to (i) assess the change in cardiovascular risk factor profile of a rural cohort over a mean period of 6.5 years; (ii) find out the factors associated with the occurrence of new cases of hypertension; (iii) validate the Indian Diabetes Risk Score, a diabetes screening tool.

Methods: A retrospective cohort study was conducted after a mean period of 6.5 years on a subsample of respondents of a study in 2003. At revisit, of the 495 original cohort, 452 (91.3%) aged 21 to 85 years were studied. The study involved the WHO STEPwise approach for data collection. Information on tobacco use, alcohol use, fruit and vegetable intake and physical activity were obtained through a pre-tested structured interview schedule (STEP 1). Physical measurements such as blood pressure, weight, height and waist circumference were taken (STEP 2).

Results: Age-adjusted mean and prevalence of cardiovascular risk factors in the baseline and present study were tobacco use 20.8% vs. 25.4%, alcohol use 20.4% vs. 36.4%, low fruit and vegetable intake 38.9% vs. 63.0%, physically less active 13.5% vs. 29.3%, body mass index 21.74 vs. 23.44 kg/m^2 (overweight 20.3% vs. 34.5%), waist circumference 82.2 vs. 86.1 cm and self reported diabetes 8.3% vs. 18.2%. Incidence rate of hypertension was 41 per 1000 person-years. Incident hypertension was significantly associated with age [O.R: 5.23; 95% C.I (2.43-11.28) for 35-54 years, 9.56; (3.62-25.29) for ≥ 55 years, 15-34 years as referent], smoking [2.46; (1.04-5.80)], high normal blood pressure [5.17; 2.66-10.05)] and abdominal obesity [3.23; (1.59-6.55)]. The Indian Diabetes Risk Score (IDRS) predicted diabetes at a cut-off ≥ 60 with a sensitivity of 85.7%, specificity of 59.1% and positive likelihood ratio of 2.1. Area Under the Curve for ROC was 0.802 (95% C.I: 0.755-0.850).

Conclusion: There is significant worsening of the cardiovascular risk factor profile of this rural cohort along with a high incidence of hypertension. The IDRS identified a substantial proportion of respondents with diabetes.

Chapter 1: Introduction

1.1 Background

Cardiovascular diseases have become a major public health problem in India and other developing countries of the world. They are now the leading cause of deaths in the world. The developing countries are now struggling with a twin burden of infectious diseases and non-communicable diseases. The cause for this was attributed to the epidemiologic transition happening at a much compressed rate as compared to that experienced by the developed nations. The worrying situation is that while the cardiovascular disease death rates are coming down in industrialized countries it is increasing in developing nations of the world. This is because the developed countries were able to translate their research in to action in the form of preventive and curative strategies. In India people are afflicted at younger age (productive years of life) as compared to those of western origin. This is due to the early onset of risk factors among Indians. The death toll among young generation is causing huge economic burden to the families of individuals as well as to the nation. In addition there are myths prevailing among the policy makers that non-communicable diseases are diseases of the urban affluent. There are limited data available to show that risk factors for cardiovascular diseases are increasing in the rural areas of India. There is an urgent need for research in rural areas to detect the trend in cardiovascular risk factors which will provide a strong base for action. This could be called as the “survey and service” approach. Timely detection and intervention will help in curtailing the upcoming cardiovascular disease outbreak in the rural areas of India.

1.2 Literature Review

The first section of literature review will discuss on the burden of cardiovascular diseases (coronary heart disease and stroke, in particular) in the world, India and Kerala. It will also provide enough evidence from different regions of the world establishing tobacco use, alcohol use, low fruit and vegetable intake, physical inactivity, hypertension, overweight and obesity, abdominal obesity, diabetes, dislipidemia, age, sex and family history of cardiovascular disease as cardiovascular risk factors. The second section will speak on the various screening tools developed in the world for identifying the likelihood of having diabetes along with a focus on Indian Diabetes Risk Score (IDRS). The review was restricted to the latest available literature, as there are numerous studies starting from the 'Framingham study' till date on cardiovascular diseases and its risk factors. Pubmed database was used to search and retrieve original articles for citation.

1.2.1 Cardiovascular diseases

Major non-communicable diseases include cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. Cardiovascular diseases (CVD) are a group of disorders of the heart and blood vessels such as coronary heart disease, hypertensive heart disease, rheumatic heart disease, inflammatory heart disease, peripheral vascular disease, congestive heart failure, congenital heart disease and stroke.[1] Coronary heart disease (CHD) and stroke constitutes a substantial proportion of the cardiovascular diseases. Coronary heart disease is caused by blockage of vessels supplying the heart due to atherosclerosis. The disruption of atheromatous plaque leads to the formation of thrombus resulting in acute myocardial infarction commonly called as heart attack.[2] Stroke is an acute cerebrovascular accident

having similar pathophysiology as coronary heart disease resulting from ischemia due to thrombosis, hemorrhage and embolism.[3]

1.2.1.1 The disease burden

1.2.1.1.1 Global scenario

Non-communicable diseases (NCDs) are now the world's biggest killers causing an estimated 35 million deaths each year (60 percent of all deaths), of which 80 percent is occurring in low and middle income countries. The World Health Organization (WHO) stated that, deaths from NCDs will increase by 17 percent over the next ten years. The greatest increase will be seen in the African region (27 percent) and Eastern Mediterranean region (25 percent). However, the highest absolute number of deaths will occur in the Western Pacific and South-East Asian regions.[4] Among NCDs, cardiovascular diseases are the leading cause of death and loss of disability adjusted life years (DALY).[5] About 17.1 million people died from cardiovascular diseases in 2004, representing 29 percent of all deaths. Of these, an estimated 7.2 million were due to coronary heart disease and 5.7 million due to stroke.[6]

1.2.1.1.2 Indian scenario

India is passing through an epidemiologic and demographic transition leading to the emergence of NCDs as a major public health problem. There has been an increasing attention on the rising burden of cardiovascular diseases in the country, from the researchers and international agencies like the WHO.[7,8] In 2003, the prevalence of coronary heart disease was estimated to be around eight to ten percent in urban areas and three to four percent in rural areas among adults older than 20 years. The figures represent a six-fold rise in urban areas

and two-fold rise in rural areas over the past 40 years.[9] A study from rural Andhrapradesh in 2004 reported that, 32 percent of all deaths were due to cardiovascular diseases.[10] Gajalakshmi and Peto by using a verbal autopsy method showed that, 39 percent of deaths in urban Chennai were from cardiovascular diseases.[11] The World Health Report 2002 stated that, cardiovascular diseases will be the largest cause of morbidity and mortality by 2020 in India. In 2020, 2.6 million people were predicted to die from coronary heart disease which will constitute 54.1 percent of all cardiovascular disease deaths.[12] Indians are experiencing cardiovascular diseases at an younger age (in their productive years) due to the onset of risk factors five to ten years earlier as compared to their western counter parts.[13,14,15,16,17] Hence, it is posing a huge economic burden to the nation representing a loss of nine billion dollars in 2005, which was projected to increase to almost 237 billion dollars by 2015.[18]

1.2.1.1.3 Kerala scenario

Kerala has made a rapid strive in the epidemiologic transition as compared to other states in India. An ongoing prospective study in seven villages of the Thiruvananthapuram district showed that, 40 percent of deaths occurred in a period of five years were due to diseases of the circulatory system. In those, 60 percent of male deaths and 40 percent of female deaths from coronary heart disease occurred before the age of 65 years.[19] These figures were much higher than that reported in other states of India.[10,11] A study based on 'The Trivandrum Stroke Registry' showed an annual incidence of stroke in urban areas to be 135 per 100,000 and in rural areas as 138 per 100,000.[20]

1.2.2 Cardiovascular risk factors

Cardiovascular diseases are multi factorial in causation with modifiable and non-modifiable risk factors. Modifiable risk factors are high blood pressure, diabetes mellitus, tobacco use, alcohol use, physical inactivity, unhealthy diet, stress, overweight/obesity and abnormal lipids.[21] The World Health Report 2002 lists six of them amongst the 10 most important risk factors accounting for a large proportion of the global burden of chronic diseases.[12] Non-modifiable risk factors are age, family history, gender and ethnicity.[21] The Interheart study showed that nine modifiable risk factors such as abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, less consumption of fruits and vegetables, high alcohol intake and physical inactivity contribute to more than 90 percent of the risk of myocardial infarction.[22] In addition, modeling of cohort studies have also demonstrated that four to five risk factors explain a major portion of the development of cardiovascular diseases.[23]

1.2.2.1 Modifiable risk factors

1.2.2.1.1 Smoking

Smoking was found to be an independent cardiovascular risk factor by several epidemiological studies across countries in the world. These studies have also observed a dose response relationship between smoking and cardiovascular diseases.[22,24,25,26] The risk of myocardial infarction drops by 50 percent within a year of smoking cessation.[26] Smoking probably acts through mechanisms which are multiple and synergistic like high serum cholesterol, thrombosis, endothelial dysfunction, insulin resistance, atherosclerosis and hemodynamic effects.[27]

1.2.2.1.2 Smokeless tobacco use

The cardiovascular effects of smokeless tobacco use were not well established as compared to smoking and the results were inconclusive and conflicting. Since snuff is the commonest variant of smokeless tobacco used, most of the studies were focused on its effect on cardiovascular diseases. A study among Swedish construction workers on snuff usage showed that, ever users had a relative risk of 1.28 for acute myocardial infarction as compared to non-users.[28] A recent meta-analysis of 11 cohort studies from 1992 to 2008 found relative risks for myocardial infarction ranging from 0.9 to 1.5 and 0.8 to 1.46 for stroke.[29] No increased risk of myocardial infarction was found among snuff users without previous history of smoking.[30] A nested case control study showed that, snuff use was not found to have higher risk of stroke than never users.[31] In India, the effect of smokeless tobacco use on cardiovascular diseases was not studied to an extent as in the western region.

1.2.2.1.3 Alcohol use

Epidemiological studies among different populations in the world have documented an inverse relationship between moderate consumption of alcohol and risk of coronary heart disease.[22] Moderate alcohol intake probably exerts its cardio protective effect by reducing high density lipoprotein and fibrinogen and increasing insulin sensitivity.[32] However, the INTERHEART study has shown a possible harm for coronary risk among South Asians.[33] This finding was subsequently replicated in a study on an Indian industrial population.[34]

1.2.2.1.4 Fruit and vegetable intake

Intake of fruits and vegetables are now recommended as part of a healthy diet. There are multiple protective constituents in fruits and vegetables like fiber, potassium, folate, vitamins and other phenolic compounds. The individuals who consume fruits and vegetables were found to have low prevalence of cardiovascular risk factors like hypertension, obesity and type2 diabetes.[35,36] Meta-analyses of cohort studies showed an inverse association between intake of fruits and vegetables and risk of coronary heart disease and stroke.[37] Intake of five or more servings of fruits and vegetables a day is recommended.[38]

1.2.2.1.5 Physical activity

Inverse linear relationship between the level of physical activity and risk of coronary heart disease was observed in both men and women.[39,40] The probable pathways through which physical activity reduces the risk of coronary heart disease are improvement in blood pressure, lipid profile, insulin sensitivity, body weight, endothelial function, coronary blood flow and changes in haemostatic and inflammatory variables.[41] The current recommendation is atleast 30 minutes of moderate intensity activities like brisk walking, cycling for five or more days a week or 20 minutes of vigorous intensity activities for three or more days a week.[42]

1.2.2.1.6 Hypertension

Hypertension induces endothelial dysfunction, exacerbates the atherosclerotic process, makes the atherosclerotic plaque unstable and increases myocardial oxygen demand through left ventricular hypertrophy. High normal blood pressure was associated with increased risk for cardiovascular disease.[43] The relative risk for myocardial infarction doubles when systolic

blood pressure shifts from the range of pre-hypertension to hypertension.[44] The seven country study showed a higher mortality risk from coronary heart disease with increasing levels of blood pressure.[45] In case of stroke, the risk almost triples for a person with hypertension as compared to a person without hypertension.[46]

1.2.2.1.7 Overweight and Obesity

Earliest finding on the association between high body mass index and cardiovascular disease rose from the analysis of Framingham heart study. The study showed overweight as an independent predictor of cardiovascular risk after adjusting for other risk factors like age, smoking, high blood pressure, high cholesterol and high blood sugar.[47] Much of the literature linking overweight and obesity with cardiovascular disease focuses on coronary heart disease as compared to stroke. These studies have reported relative risks ranging from 1.2 to 3.6 for the occurrence of new cases of coronary heart disease.[48,49] Their role as a risk factor for stroke remains controversial with differences in sexes and type of stroke. Field et al reported that, men with body mass index more than or equal to 30 kg/m^2 had a relative risk of 2.0 for stroke as compared to those with body mass index less than 25 kg/m^2. However, increased risk was not seen in women.[50]

1.2.2.1.8 Abdominal obesity

Abdominal obesity, clinically referred to as central obesity, is the accumulation of abdominal fat resulting in increase in the waist size. Increase in waist circumference predisposes individuals to insulin resistance, which is a major feature of type2 diabetes and an independent cardiovascular risk factor, through secretion of adipokines and raise in serum resistin levels from metabolically active intra abdominal fat.[51] Waist circumference of $\geq$ 90

cm was found to have a relative risk of 1.89 for acute coronary events in men.[52] This one to one relationship was shown to be consistent in all 63 geographical regions involved in a large international trial called the International Day for the Evaluation of Abdominal Obesity (IDEA) study. The odds ratios for one standard deviation increment in waist circumference ranged from 1.27 to 1.93 in men and from 1.19 to 1.51 in women.[53] However, the cut off level predicting cardiovascular risk differs among sexes and ethnic groups. South Asians were found to be at risk of developing coronary heart disease at a lower cut off than people living in the western region.[54]

1.2.2.1.9 Diabetes

Several prospective and cross sectional studies across the world have well established that diabetes is a major cardiovascular risk factor.[55] Two main processes which lead to cardiovascular disease among diabetics are atherosclerosis and hypertension. The individuals with diabetes have two to four times the risk of developing cardiovascular disease as compared to those without diabetes.[56] A study from south India showed that, prevalence of coronary heart disease rose with increasing levels of blood sugar. The risk increased from 9.1 percent in people with normal glucose tolerance to 21.4 percent in diabetics.[57] Also, diabetics have a high prevalence of other cardiovascular risk factors like lipid disorders, obesity, insulin resistance and hypertension.[58]

1.2.2.2 Non-modifiable risk factors

1.2.2.2.1 Age

Getting older is in itself an independent risk for developing cardiovascular diseases.[21] The incidence rate of acute myocardial infarction rose with age in people with or without a pre-existing cardiovascular risk factor.[59] This positive association also held for the risk of onset of stroke.[60]

1.2.2.2.2 Sex

There is a significant difference in the cardiovascular risk between sexes.[61] The progression rate of cardiovascular diseases was found to be markedly higher in men than in age-matched premenopausal women.[62] This could be due to the effect of male sex hormones and difference in cardiovascular risk factors between the sexes.[63]

1.2.2.2.3 Genetic factors

Family history of cardiovascular disease puts a person at high risk for developing cardiovascular events.[21] The cardiovascular risk was found to be two fold for people with parental history of cardiovascular disease as compared to people without.[64] This relationship was consistent for both maternal and paternal history of cardiovascular disease.[65]

1.2.3 Diabetes screening tools in the world

Globally, more than 30 screening strategies have been developed to detect impaired glucose tolerance, diagnosed and undiagnosed diabetes in the general population. These include risk scores, prediction models, risk calculators, logistic regression equations and clinical rules. Majority of them include non-biochemical risk factors such as age, body mass index, waist

circumference, family history of diabetes, history of antihypertensive medication, intake of fruits and vegetables, history of gestational diabetes, smoking, physical activity, history of hypertension and alcohol consumption. Three diabetic risk scores have been developed predominantly from Indian population.[66,70,71]

1.2.3.1 The Indian Diabetes Risk Score (IDRS)

The Indian Diabetes Risk Score[66] was the first diabetes screening tool to be developed in India. It was derived from the Chennai Urban Rural Epidemiology Study (CURES), an ongoing epidemiological study on a representative population of Chennai, Tamilnadu. It has four variables such as age, abdominal obesity, family history of diabetes and physical activity. Each variable has 3 categories with scores ranging from 0 to 30. The overall minimum score is 0 and the maximum score is 100. The published cutoff value was ≥ 60, which had a sensitivity of 72.5 percent, specificity of 60.1 percent, positive predictive value of 17 percent, negative predictive value of 95.1 percent and accuracy of 61.3 percent in its original evaluation. The tool was validated in the same population from which it was developed.

1.2.4 Objectives

Major objectives

1. To assess the change in cardiovascular risk factor profile over a mean period of 6.5 years of a rural cohort in Thiruvananthapuram district, Kerala.

2. To find out the factors associated with the occurrence of new cases of hypertension.

Minor objective

To validate Indian Diabetes Risk Score (IDRS), a diabetes screening tool.

1.2.5 Rationale for the study

Rationale for the study was explained in terms of three objectives of the study.

1.2.5.1 First major objective

Cardiovascular diseases have assumed epidemic proportions in India and other developing countries of the world. This is being accelerated by ageing population and increasing trends in major cardiovascular risk factors like smoking, sedentary lifestyle, hypertension, diabetes and hypercholesterolemia.[67] However, much of this understanding has come from studies in urban areas with few from rural areas where more than 70 percent of India's population live. There are two ways by which temporal changes or secular trends in cardiovascular risk factors in the general population can be understood. They are (i) Cross sectional surveys at different time periods in a same geographical location. (ii) Longitudinal studies. In India, studies reporting secular trends or temporal changes in cardiovascular risk factors have inherent limitations (i) data from different regions of the country or within a state were

compared. (ii) sampling strategies were slightly different. (iii) focus was on a single risk factor. (iv) studies in rural areas are limited. Knowing the risk factor change happening in the general population would help in formulating strategies for prevention of the upcoming cardiovascular outbreak. To the best of my knowledge, there are no studies from rural areas of India reporting change in the level of risk factors for cardiovascular diseases in a cohort.

1.2.5.2 Second major objective

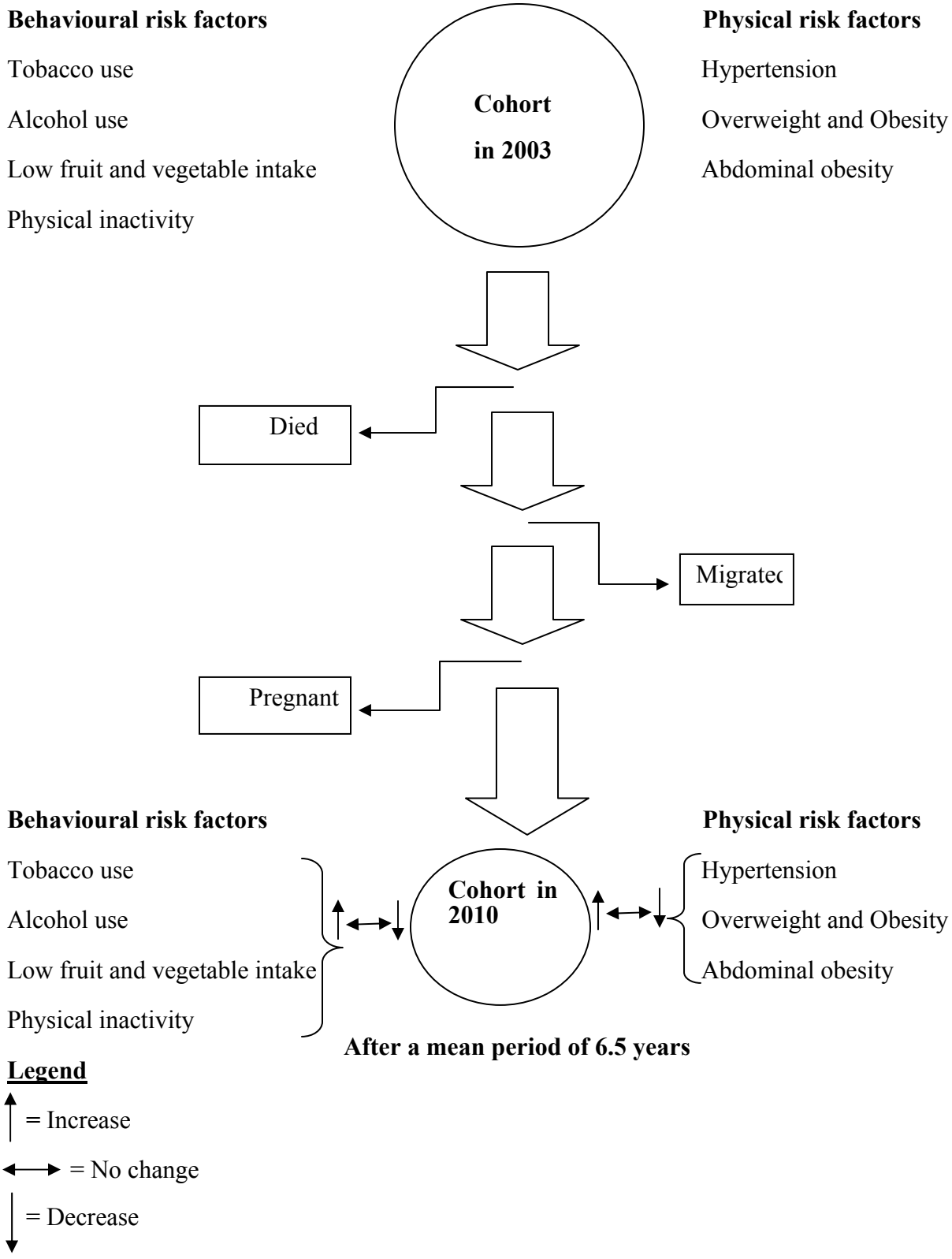
The prevalence of hypertension and the risk factors associated were sufficiently studied in India. However, data on incident hypertension is limited. Also, these studies report several lifestyle related factors to be associated with hypertension. While cross sectional studies demonstrate association, causality is better determined by longitudinal studies. Hence, an attempt was made to report incidence of hypertension and to investigate the risk factors associated.

1.2.5.3 Minor objective

In India the existing burden of diabetes will triple between 1995 and 2025.[68] The worrying situation is that, 50 to 60 percent of individuals with hyperglycemia remain undiagnosed due to lack of awareness, lack of resources and poor health infrastructure.[15] Around 70 percent of urban Type2 diabetes is diagnosed but in rural areas more than 70 percent remain undetected. Universal screening for diabetes in a population is not practical and recommended. A cost effective alternative would be to identify risk factors in the individuals that would predict type2 diabetes.[69] Moreover, screening tools to detect diabetes that were developed in Caucasian populations are not necessarily applicable to South Asians, who are ethnically distinct. Till date, three diabetes risk scores[66,70,71] were developed in Indian population. The

Indian Diabetes Risk Score (IDRS) was the first diabetes screening tool to be developed in India. The IDRS was chosen for validation for two main reasons (i) The score uses four simple, strong and non-invasive variables such as age, waist circumference, physical activity and family history of diabetes which are possible to measure in a primary health care setting. (ii) External validation of the score was not attempted.

1.2.6 Conceptual Framework



Chapter 2: Methodology

The present study is a retrospective cohort study involving 452 respondents of the original cohort (n = 495) in a rural community of Thiruvananthapuram district, Kerala. These 452 were revisited after a mean period of 6.5 years to look for the change happened in their cardiovascular risk factor profile. The baseline data collection of the present study and how the cohort was formed were described before explaining the methodology of the present study.

2.1 Baseline data collection of the present study

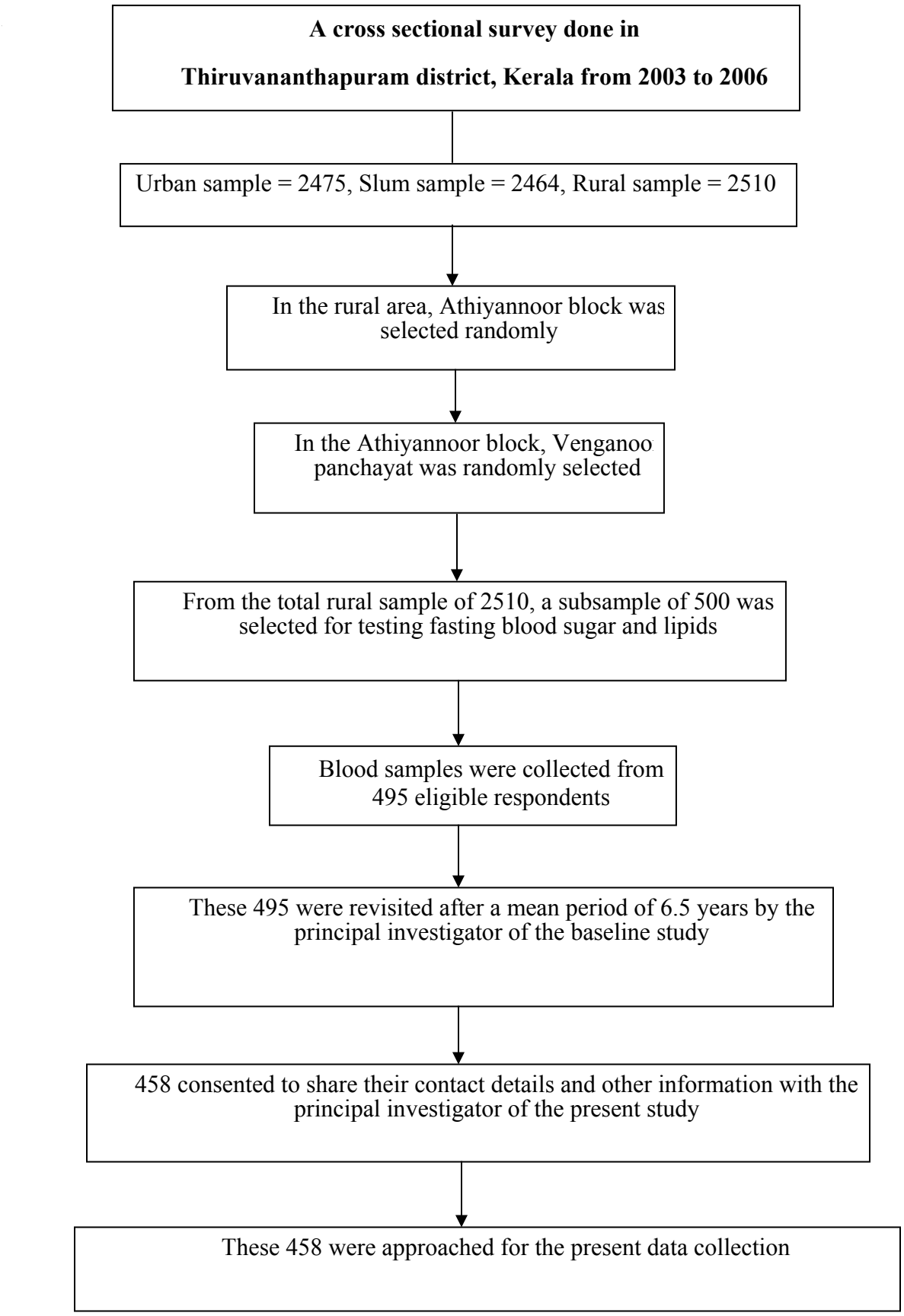
The baseline data collection of the present study was described elsewhere.[72] In brief, the study was a cross sectional survey conducted by the Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology in the urban, slum and rural areas of Thiruvananthapuram district, Kerala from 2003 to 2006. A total of 7449 respondents (urban = 2475, slum = 2464 and rural = 2510) between the ages of 15 and 64 years were selected for the study. Kish method was used to select one individual from each household.[73] In the rural area, one of the 19 blocks called **'Athiyannoor community development block'** was selected randomly. The block was divided in to six panchayats and one of them was selected randomly. The selected panchayat called **'Venganoor panchayat'** was divided in to 15 wards and eight of them were randomly selected. From the total rural sample of 2510, a subsample of 500 (stratified by age and sex) was selected through systematic random sampling for biochemical analysis by the coordinating centre of the study (Indian Council of Medical Research (ICMR), New Delhi). Blood samples were collected from 495 eligible respondents of the subsample of 500. The study involved the WHO **'STEPwise approach'** for data collection.[74] Information on socio-

demographic characteristics like age, sex, education, occupation and behavioural risk factors like tobacco use, alcohol use, fruit and vegetable intake and physical activity were obtained using a pre-tested WHO Interview schedule version 1.4 (adapted to the Indian setting) (STEP 1). Physical measurements such as height, weight, waist circumference and blood pressure were also measured (STEP 2). Blood samples were drawn for testing fasting blood sugar and lipids (STEP 3).

2.2 Steps involved in formation of the cohort

The 495 respondents of the total rural sample (n = 2510) who underwent blood testing for fasting blood sugar and lipids were revisited by the principal investigator of the baseline study after a mean period of 6.5 years (2003 to 2010). The consent to share their contact details and other data collected in the baseline study with the principal investigator of the present study was obtained from 458 respondents (excluding 17 died, four pregnant, 16 migrated). The baseline data of these 458 respondents was alone shared with the principal investigator of the present study. These 458 were then approached for data collection for the present study. The above described was given diagrammatically in Figure 2.1.

Figure 2.1 Flow chart showing the baseline data collection and formation of the cohort



Methodology of the present study

2.3 Study design

The study was a community based Retrospective cohort study.

2.4 Study setting

The study was conducted in eight wards of Venganoor panchayat of the Athiyannoor community development block in Thiruvananthapuram district, Kerala.

2.5 Sample size and Sample selection procedure

The 495 of the total rural sample (n = 2510) in the baseline study who underwent blood testing for fasting blood sugar and lipids was considered as the sampling frame for the present study. Of which, 458 have consented to share their contact details and other information with the principal investigator of the present study. This 458 was considered as the sample size for the present study.

2.6 Inclusion criteria

Respondents who consented to share their contact details and other information with the principal investigator of the present study.

2.7 Exclusion criteria

- Respondents who died before the start of the present study.
- Respondents who migrated before the start of the present study.
- Pregnant women.

2.8 Data collection

2.8.1 Training of the field investigators

The principal investigator employed two field investigators (one male and one female) for data collection. They were intensively trained by a master trainer and the principal investigator on administering the consent form, interview schedule and taking physical measurements such as blood pressure, height, weight and waist circumference using WHO STEPS surveillance manual.[75] The training was divided in to class room training and field trial. The total period of training was for seven days. The class room training was organized at the Achutha Menon Centre for Health Science Studies for two days and field trial was conducted in the wards of Venganoor and Vizhinjam panchayat (which does not come under the purview of study area) for a period of five days.

2.8.2 Data collection period

Data collection was undertaken from 10th July 2010 to 15th September 2010 at households of the respondents.

2.8.3 Data collection method

A fresh informed consent to participate in the present study was obtained. The data collection was carried using the WHO 'Stepwise approach' as the baseline study[74].

2.8.3.1 STEP 1: Interview

Information on socio-demographic characteristics such as age, sex, education, occupation and behavioural risk factors like tobacco use, alcohol use, fruit and vegetable intake and physical activity were obtained by administering the pre-tested WHO Interview schedule version 1.4 (adapted to the Indian setting) (Appendix IV). In addition to the existing

questions, information on physical exercise, family history of diabetes and family history of hypertension were obtained.

2.8.3.2 STEP 2: Physical measurements

In order to avoid inter-observer and inter-instrument bias, all physical measurements were taken by a single observer with single instruments. The weighing scale was calibrated using a standard 3 kg weight and an error of - 0.1 kg was adjusted in the measurements taken. A calibrated new blood pressure apparatus was purchased. Physical measurements such as blood pressure, weight and waist circumference were taken for all the respondents. While, height was measured only for the respondents who were in the age group of 15 to 24 years during the baseline study, expecting change after 6.5 years. The details on the steps involved in taking measurements were attached as Appendix VII. A brief description on the measurements taken was presented below.

(i) Blood pressure

Three readings of blood pressure were taken in the right arm in a seated position. For blood pressure measurement, OMRON automatic blood pressure monitor (OMRON SEM-1, Omron Corporation, Kyoto, Japan) was used as per the WHO recommendation.[75] First reading was taken after explaining the purpose of the study and getting the informed consent. Second reading was measured immediately after administering the interview schedule. Third reading was taken after taking anthropometric measurements such as height, weight and waist circumference. For analysis, average of three readings was taken if there was a difference of more than 10 mmHg between the first two readings or else the average of first two readings was considered.

(ii) Height

Height was measured using a non-stretchable height measuring tape after removing the foot wear, looking straight ahead and standing erect with feet together, heels against the wall and knees straight.

(iii) Weight

Weight was taken using the SECA electronic weighing scale after removing the foot wear with one foot on either side of the scale, standing still, facing forward and placing arms on the side.

(iv) Waist circumference

Waist circumference was measured using the SECA constant tension tape at the midpoint between last palpable rib and top of iliac crest. The measurement was taken at normal expiration.

2.9 Data storage

The collected data were directly entered in to SPSS for Windows version 16.0. The hard copies of data collected were stored in the safe custody of the principal investigator.

2.10 Data analysis and Statistical methods

The data collected were analyzed using SPSS for Windows version 16.0 and R version 2.12.0. Continuous variables were presented as mean ± 1 standard deviation and categorical variables as percentages. Risk factors in the baseline and present study were compared after adjusting for age using direct standardization method (Kerala census 2001). For the risk

factor comparison, if there was overlap in the confidence interval of a variable in the baseline and present study then it was considered to be not significant at $p < 0.05$. To compare the baseline characteristics of respondents who developed hypertension with those who did not, Pearson Chi-square test was used for categorical variables and Independent-Sample T test for continuous variables. In bivariate analysis and logistic regression modeling, incident hypertension was taken as the dependent variable and independent variables were chosen from the baseline study. Measure of association was presented as odds ratio with 95% confidence interval and p value. Forward step wise logistic regression method was used for modeling. Interaction terms were not allowed. To compare the Indian Diabetes Risk Score (IDRS) characteristics of the respondents with diabetes and those without, Pearson Chi-square test was used for proportions and Independent-Samples T test for means. The results of validation of the Indian Diabetes Risk Score (IDRS) were presented as sensitivity, specificity, positive and negative predictive value, positive and negative likelihood ratio for different cut off values. The overall usefulness of the risk score was tested using Receiver Operating Characteristic (ROC) curve by plotting sensitivity against 1-specificity and estimating the Area Under the Curve (AUC) with 95% confidence interval and p value. P values less than 0.05 were considered to be significant for all analysis.

2.11 Definitions used

(1) Tobacco use: Those who used any form of tobacco in the last one month were defined as tobacco user.

(2) Smoking: Those who smoked in the last one month were defined as current smoker.

(3) Smokeless tobacco use: Those who used smokeless tobacco in the last one month were defined as smokeless tobacco user.

(4) Alcohol use: Those who consumed an alcoholic drink in the last 12 months were defined as current alcohol user.

(5) Low fruit and vegetable intake: Those who consumed less than five servings of fruits and vegetables in a day.[38]

(6) Physical activity: Physical activity was estimated in three domains namely work, transport and recreation. Total time spent in physical activity during a typical week, number of days and intensity of the physical activity were taken in to account in categorizing respondents in to having high, moderate and low physical activity. METs (Metabolic Equivalents) were used to express the intensity of physical activity. MET is defined as the energy cost of sitting quietly and is equivalent to a caloric consumption of one kcal/kg/hour[73]. Formulas used for physical activity categorization was given as Appendix VI.

Domain	MET value
Work	Moderate MET value = 4.0 Vigorous MET value = 8.0
Transport	Cycling and Walking MET value = 4.0
Recreation	Moderate MET value = 4.0 Vigorous MET value = 8.0

Source: WHO: GPAQ analysis guide, 2008

Respondents with high and moderate physical activity were clubbed in to a category called "More active" and respondents with low physical activity were labeled as "Less active".

(7) High normal blood pressure: Systolic blood pressure 130 - 139 mmHg and/or diastolic blood pressure 85 - 89 mmHg.[76]

(8) Hypertension: Systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg and/or on anti-hypertensive medications.[77]

(9) Body Mass Index (BMI): Weight (kg)/Height in m^2.

(10) Overweight: BMI ≥ 25 kg/m^2.[78]

(11) Obesity: BMI ≥ 30 kg/m^2.[78]

(12) Abdominal obesity: There are multiple cut-off values suggested for defining abdominal obesity. In the present study, an ethnic specific (Asian Indians) cut-off of ≥ 85 cm for men and ≥ 80 for women was used.[79]

(13) Self reported diabetes: High blood sugar or diabetes as reported by a physician or other health worker.

(14) Diabetes: Fasting blood sugar ≥ 126 mg/dl and/or anti-diabetic medications.[80]

(15) Hypercholesterolemia: Total cholesterol ≥ 200 mg/dl.[81]

(16) Hypertriglyceridemia: Triglycerides ≥ 150 mg/dl.[81]

(17) Sensitivity: (True positives/Total positives)*100.[82]

(18) Specificity: (True negatives/Total negatives)*100.[82]

(19) Positive predictive value: (True positives/Tested positives)*100.[82]

(20) Negative predictive value: (True negatives/Tested negatives)*100.[82]

(21) Positive likelihood ratio: Sensitivity/1 - Specificity.[82]

(22) Negative likelihood ratio: 1 - Sensitivity/Specificity.[82]

2.12. Outcome variable

Incident hypertension was taken as the outcome variable.

2.13. Independent variables

Independent variables were taken from the baseline study.

I. Socio-demographic characteristics

- Age
- Sex
- Years of schooling

II. Behavioural characteristics

- Smoking
- Alcohol use
- Fruit and vegetable intake
- Physical activity

III. Physical characteristics

- High normal blood pressure
- Overweight
- Abdominal obesity

IV. Biochemical characteristics

- Diabetes
- Hypercholesterolemia
- Hypertriglyceridemia

2.14 Ethical considerations

Ethical clearance for the study was obtained from the Institutional Ethics Committee (IEC) of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvanathapuram, Kerala. Waist circumference for the women respondents was taken by the female field investigator in a closed space in their household.

Chapter 3: Results

This chapter describes the results of data analysis undertaken. The data analysis was carried out by keeping the objectives of the study in background. In brief, the study was looking at changes in the mean level and proportion of various cardiovascular risk factors in a rural cohort over a mean period of 6.5 years. The study was also attempting to find out the incidence of hypertension and the risk factors associated. In addition to the above mentioned, the study was trying to validate the Indian Diabetes Risk Score (IDRS), a diabetes screening tool.

Please Note: Baseline study refers to the study conducted in year 2003 and present study refers to the study conducted in year 2010.

The present study was conducted on an average 6.5 years after the baseline study. At revisit, of the total sample size of 458, six refused to participate in the study. The overall response rate in the present study was 98.7 percent (452/458), 214/217 (98.6 percent) in men and 238/241 (98.8 percent) in women.

3.1 Baseline socio-demographic details of the respondents evaluated in the baseline study

Age, education, years of schooling and occupation of the respondents evaluated in the baseline study was presented in Table 3.1.

The overall mean age of respondents was 39.5 ± 14.3 years, men: 39.4 ± 13.6 years and women: 39.6 ± 15.0 years. The age ranged from 15 to 67 years in men and from 15 to 79 years in women. In men, 98.1 percent had some form of formal schooling as compared to 93.7 percent women.

Table 3.1: Baseline socio-demographic characteristics of the respondents evaluated in the baseline study

Characteristics	Men (n = 214)	Women (n = 238)	Total (n = 452)
Age (years)			
15 - 24	43 (20.1)	37 (15.5)	80 (17.7)
25 - 34	38 (17.8)	62 (26.1)	100 (22.1)
35 - 44	51 (23.8)	45 (18.9)	96 (21.2)
45 - 54	41 (19.2)	55 (23.1)	96 (21.2)
≥ 55	41 (19.2)	39 (16.4)	80 (17.7)
Education[a]			
No formal schooling	4 (1.9)	15 (6.3)	19 (4.2)
Less than primary school	61 (28.5)	75 (31.5)	136 (30.1)
Primary school completed	76 (35.5)	70 (29.4)	146 (32.3)
Secondary school completed	30 (14.0)	44 (18.5)	74 (16.4)
High school completed	17 (7.9)	16 (6.7)	33 (7.3)
University/College	26 (12.1)	18 (7.6)	44 (9.7)
Years of schooling			
< 10	92 (43.0)	121 (50.8)	213 (47.1)
≥ 10	122 (57.0)	117 (49.2)	239 (52.9)
Occupation			
Unskilled	79 (36.9)	3 (1.3)	82 (18.1)
Self employed	41 (19.2)	21 (8.8)	62 (13.7)
Housewife/Homemaker	1 (0.5)	179 (75.2)	180 (39.8)
Retired	10 (4.7)	2 (0.8)	12 (2.7)
Student	28 (13.1)	18 (7.6)	46 (10.2)
Unemployed[b]	16 (7.5)	9 (3.8)	25 (5.6)
Others[c]	39 (18.2)	6 (2.5)	45 (10.0)

Source: Primary survey, 2003 Thiruvananthapuram.

Figures in parenthesis are percent. a: Primary school refers to 7th standard, Secondary school refers to 10th standard and High school refers to 12th standard. b: Includes able to work and unable to work. c: Includes professional, government and non-government employee.

The mean years of schooling was almost similar in men (8.8 ± 4.0) and women (8.1 ± 4.1). The years of schooling ranged from 0 to 18 in both men and women. The largest proportion of

men (36.9 percent) was involved in unskilled work, while women were predominantly housewives (39.8 percent).

3.2 Comparison of cardiovascular risk factors in the baseline and present study

The proportion and mean level of risk factors in the baseline and present study were age-adjusted and compared.

3.2.1 Tobacco use

The overall, age and sex wise prevalence of smoking and smokeless tobacco use in the baseline and present study were shown in Table 3.2.

Table 3.2: Overall, age and sex wise prevalence of smoking and smokeless tobacco use in the baseline and present study

Smoking[a]					**Smokeless tobacco use**				
Year 2003		Year 2010		**P[c]**	Year 2003		Year 2010		**P[c]**
Age (yrs)[b]	**%**	**Age (yrs)[b]**	**%**	**ratio**	**Age (yrs)[b]**	**%**	**Age (yrs)[b]**	**%**	**ratio**
15 – 24	6.2	21 - 30	15.0	**2.42**	15 - 24	8.8	21 - 30	15.0	1.70
25 – 34	12.0	31 - 40	9.0	0.75	25 - 34	9.0	31 - 40	15.0	1.67
35 – 44	18.8	41 - 50	19.8	1.05	35 - 44	5.2	41 - 50	9.4	1.81
≥ 45	18.2	> 50	17.6	0.97	≥ 45	16.5	> 50	23.3	1.41
Total	14.1	**Total**	16.1	1.14	**Total**	11.2	**Total**	15.7	1.40
Men	29.8	**Men**	32.9	1.10	**Men**	18.1	**Men**	26.1	1.44
Women	0	**Women**	0	0	**Women**	5.4	**Women**	5.9	1.09

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

Respondents in the age groups of 2003 are now in the corresponding age groups of 2010. a: Smoking data are for men only. b: Percents do not add to 100% as they are percent within each age group c: Prevalence ratio. Prevalence ratios compare smokers/smokeless tobacco users in 2010 with smokers/smokeless tobacco users in 2003.

The overall prevalence of any form of tobacco use increased from 20.8 percent in 2003 to 25.4 percent in 2010, men: 38.3 percent to 46.0 percent, women: 5.4 percent to 5.9 percent. The greatest increase in the prevalence of smoking was seen among men in the young aged (15-24 yrs). The increase in the prevalence of smokeless tobacco use was 30 percent higher in men than women.

3.2.2 Alcohol use

The overall, age and sex wise prevalence of alcohol use in the baseline and present study were shown in Table 3.3.

Table 3.3: Overall, age and sex wise prevalence of alcohol use in the baseline and present study

Year 2003		Year 2010		
Age (yrs)[a]	**%**	**Age (yrs)[a]**	**%**	**Prevalence ratio**
15 - 24	11.2	21 - 30	32.5	**2.90**
25 - 34	21.0	31 - 40	36.0	1.71
35 - 44	31.2	41 - 50	46.9	1.50
≥ 45	20.5	> 50	34.1	1.66
Total	20.4	**Total**	36.4	1.78
Men	41.6	**Men**	67.4	1.62
Women	2.0	**Women**	7.5	**3.75**

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

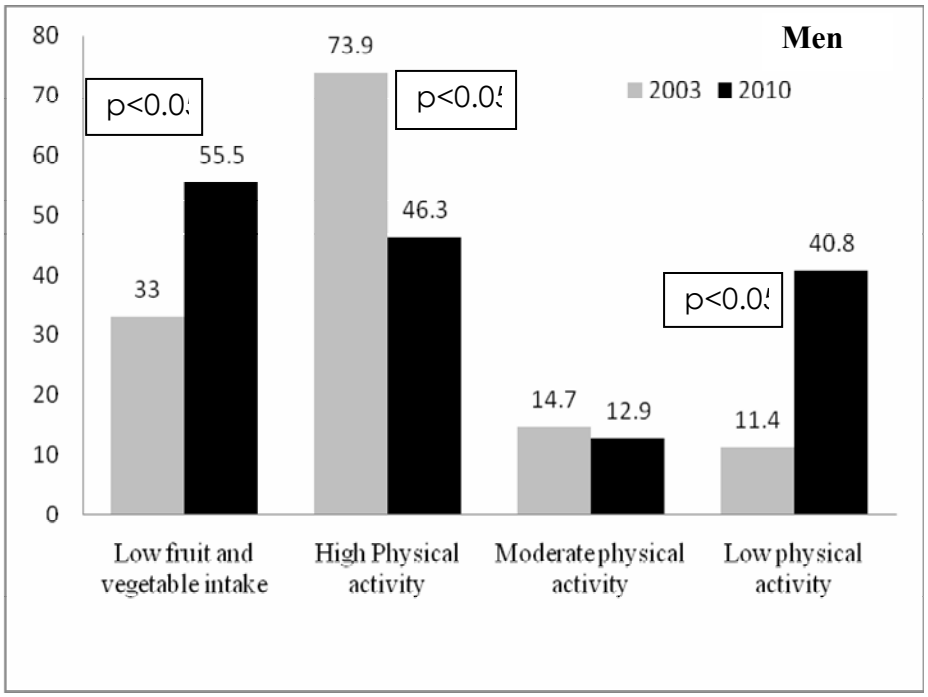
Respondents in the age groups of 2003 are now in the corresponding age groups of 2010. a: Percents do not add to 100% as they are percent within each age group. Prevalence ratios compare alcohol users in 2010 with alcohol users in 2003.

The increase in prevalence of alcohol use was seen in all ages. However, highest increase was observed in the young aged (15-25 yrs). The rise in the alcohol prevalence among women was almost 200 percent higher than that of men.

3.2.3 Low fruit and vegetable intake and Physical activity

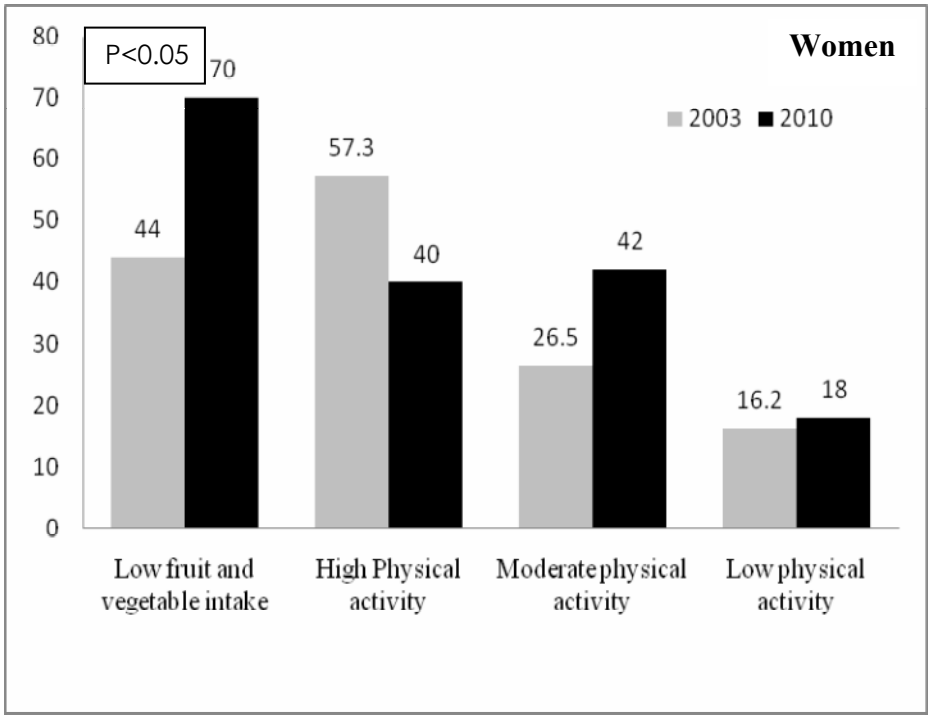
The overall prevalence of low fruit and vegetable intake increased significantly from 38.9 percent to 63 percent. There was a significant reduction in the overall high physical activity from 65.9 percent to 43 percent and increase in the low physical activity from 13.5 percent to 29.3 percent.

Figure 3.1: Age-adjusted prevalence of low fruit and vegetable intake and physical activity among men in the baseline and present study



Source: Primary survey, 2003 and 2010 Thiruvananthapuram.
Figures on top of the bars are percent.

Figure 3.2: Age-adjusted prevalence of low fruit and vegetable intake and physical activity among women in baseline and present study



Source: Primary survey, 2003 and 2010 Thiruvananthapuram.
Figures on top of the bars are percent.

The increase in the prevalence of low fruit and vegetable intake was nine percent higher in men (68 percent) as compared to women (59 percent). There was no significant change in the levels of physical activity in women (Figures 3.1 and 3.2).

3.2.4 Mean values of blood pressure, body mass index and waist circumference

Interestingly, the overall mean systolic and diastolic blood pressure did not show a significant change in spite of significant increase in the overall mean body mass index and waist circumference. The increase in the mean body mass index was higher among women as compared to men, while the reverse was seen with the waist circumference. It is noteworthy to mention that, the mean waist circumference in men has shifted from low risk range (< 85 cm) to high risk range (≥ 85 cm) (Table 3.4).

Table 3.4: Age-adjusted mean level of blood pressure, body mass index and waist circumference in the baseline and present study

Risk factors	Year 2003	Year 2010
Systolic blood pressure (mmHg)		
Total	129.6 ± 18.7	130.1 ± 20.7
Men	131.0 ± 18.8	132.9 ± 21.2
Women	128.4 ± 18.6	127.6 ± 20.1
Diastolic blood pressure (mmHg)		
Total	79.6 ± 11.4	79.7 ± 10.2
Men	78.9 ± 12.1	80.5 ± 11.1
Women	80.3 ± 10.8	79.1 ± 09.3
Body mass index (kg/m^2)		
Total	21.74 ± 4.0	23.44 ± 4.3*
Men	20.97 ± 3.8	22.49 ± 3.9*
Women	22.47 ± 4.1	24.33 ± 4.4*
Waist circumference (cm)		
Total	82.2 ± 11.5	86.1 ± 11.4*
Men	79.2 ± 11.2	84.9 ± 11.7*
Women	85.1 ± 11.1	87.3 ± 11.1

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.
Values are given as mean ± standard deviation. * $p < 0.05$ versus year 2003.

3.2.5 Prevalence of hypertension, overweight, obesity, abdominal obesity and self reported diabetes

To the surprise, the overall prevalence of diabetes has significantly increased while the prevalence of hypertension has shown a fall. This was consistent in women but not in men. The increase in the overall prevalence of self reported diabetes (prevalence ratio: 2.19) was 100 percent higher than the rise seen in abdominal obesity (prevalence ratio: 1.20) and 50 percent more than that found in overweight (prevalence ratio: 1.70) (Table 3.5).

Table 3.5: Age-adjusted prevalence of hypertension, overweight, obesity, abdominal obesity and self reported diabetes in the baseline and present study

Risk factors	Year 2003	Year 2010
Hypertension		
Total	31.2 (26.4 - 36.8)	29.2 (24.7 - 35.2)
Men	30.9 (24.0 - 39.3)	31.6 (24.5 - 41.7)
Women	31.1 (24.6 - 39.3)	27.4 (22.1 - 36.0)
Overweight		
Total	20.3 (16.5 - 24.9)	34.5 (28.9 - 41.7)*
Men	12.9 (8.7 - 18.6)	25.0 (18.7 - 34.4)*
Women	27.4 (21.2 - 35.4)	43.6 (34.4 - 56.1)
Obesity		
Total	2.8 (1.5 - 5.0)	5.9 (4.1 - 9.5)
Men	2.4 (0.9 - 5.6)	3.5 (1.6 - 9.4)
Women	3.2 (1.3 - 7.0)	8.0 (5.1 - 14.9)
Abdominal obesity		
Total	49.8 (43.6 - 56.7)	59.7 (52.2 - 68.6)
Men	33.9 (26.8 - 42.5)	45.1 (36.6 - 56.5)
Women	64.7 (54.8 - 76.1)	73.7 (61.5 - 89.2)
Self reported diabetes		
Total	8.3 (5.9 - 11.4)	18.2 (14.6 - 23.3)*
Men	7.6 (4.6 - 12.3)	17.5 (12.5 - 25.7)*
Women	8.8 (5.5 - 13.8)	19.0 (13.9 - 27.6)*

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.
Values are given as percent (95% confidence interval). *$p < 0.05$ versus year 2003.

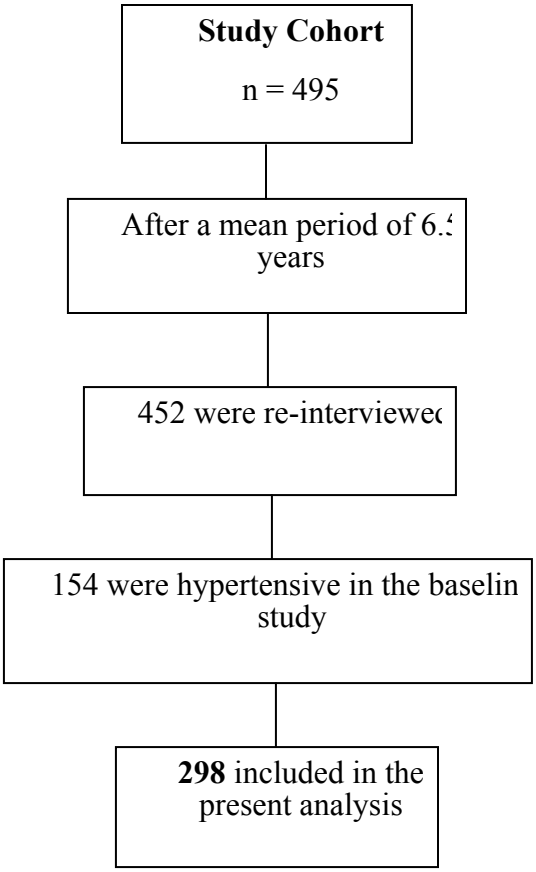
Overall inference from the above tables and figures: It was observed that, although women had higher burden of most of the risk factors (except for tobacco use, alcohol use and hypertension) than men at the baseline study, the largest increase was observed in men than women.

3.3 Incidence of Hypertension and the factors associated

3.3.1 Incidence of hypertension

The flow of respondents included in the analysis for incidence of hypertension was shown in Figure 3.3. In the total sample size of 452, about 154 were hypertensive in the baseline study. After excluding them, the remaining 298 were included in the present analysis. During a mean period of 6.5 years, 70 developed hypertension. The incidence rate was 41 per 1000 person-years; men: 45 per 1000 person-years and women: 38 per 1000 person-years. The annual cumulative incidence was 36 per 1000; men: 39 per 1000 and women: 34 per 1000. The proportion of pre-hypertensives in the baseline study that developed hypertension (32.4 percent) was significantly higher than that of normotensives (10.1 percent), $p < 0.001$.

Figure 3.3: Flow of respondents included in the analysis for incidence of hypertension



The respondents who developed hypertension were older, had higher systolic blood pressure, diastolic blood pressure, body mass index, waist circumference, fasting blood sugar, total cholesterol and triglycerides and larger proportion were smokers as compared to those who did not develop hypertension. Alcohol use, fruit and vegetable intake, physical activity and high density lipoprotein (HDL) cholesterol were not significantly different between the two groups (Table 3.6).

Table 3.6: Baseline characteristics of the respondents by the presence or absence of incident hypertension

Characteristics	Not developed hypertension	Developed hypertension	p value
n	228	70	
Age	33.3 ± 13.0	45.3 ± 12.6	**< 0.001**
Smoking (%)	12.3	25.7	**0.026**
Alcohol use (%)	19.7	28.6	0.137
Low fruit and vegetable intake (%)	40.4	42.9	0.781
Physically less active (%)	12.3	14.3	0.683
Systolic blood pressure (mmHg)	118.7 ± 11.0	128.2 ± 8.2	**< 0.001**
Diastolic blood pressure (mmHg)	73.8 ± 7.9	80.0 ± 6.0	**< 0.001**
Body Mass Index (kg/m^2)	20.89 ± 3.91	22.83 ± 3.97	**< 0.001**
Waist circumference (cm)	79.6 ± 10.4	86.4 ± 11.9	**< 0.001**
Fasting blood sugar (mg/dl)	95.9 ± 27.6	117.8 ± 52.2	**< 0.001**
Total cholesterol (mg/dl)	198.2 ± 39.1	218.0 ± 40.9	**< 0.001**
Triglycerides (mg/dl)	94.9 ± 52.3	134.7 ± 78.3	**< 0.001**
HDL cholesterol* (mg/dl)	46.4 ± 10.5	44.0 ± 10.6	0.097

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.
Values are given as mean ± standard deviation unless otherwise specified. *HDL: High Density Lipoprotein. $p < 0.05$ was considered significant.

3.3.2 Factors associated with incident hypertension

3.3.2.1 Bivariate analysis

Independent variables were taken from the baseline study to find their association with incident hypertension. For each of them the magnitude of risk associated with incident hypertension was presented in the form of odds ratio (O.R) without adjusting for other variables. Age, smoking, high normal blood pressure, overweight, abdominal obesity, diabetes, high total cholesterol and triglycerides were found to be significantly associated with incident hypertension (Table 3.7).

Table 3.7: Results of bivariate analysis: factors associated with incidence of hypertension

Risk factors	Proportion of hypertension (%)	Unadjusted O.R	95% C.I	p value
Age (years)				
15-34	8.6	**Referent**		
35-54	35.5	5.83	2.93 - 11.62	**< 0.001**
≥ 55	48.6	10.06	4.26 - 23.76	**< 0.001**
Sex				
Female	21.8	**Referent**		
Male	25.4	1.22	0.71 - 2.08	0.470
Years of schooling				
≥ 10 years	20.2	**Referent**		
< 10 years	27.4	1.49	0.87 - 2.55	0.148
Smoking				
No	20.6	**Referent**		
Yes	39.1	2.47	1.27 - 4.81	**0.008**
Alcohol use				
No	21.5	**Referent**		
Yes	30.8	1.63	0.88 - 3.0	0.120

Fruit and vegetable intake*				
≥ 5 servings/day	22.7	**Referent**		
< 5 servings/day	24.6	1.11	0.65 - 1.91	0.709
Physical activity				
More active	23.1	**Referent**		
Less active	26.3	1.19	0.55 - 2.59	0.660
High normal B.P				
No	15.1	**Referent**		
Yes	44.2	4.45	2.52 - 7.86	**< 0.001**
Overweight				
No	20.2	**Referent**		
Yes	39.2	2.54	1.34 - 4.83	**0.004**
Abdominal obesity				
No	13.3	**Referent**		
Yes	35.0	3.51	1.98 - 6.25	**< 0.001**
Diabetes				
No	19.8	**Referent**		
Yes	47.5	3.67	1.84 - 7.34	**< 0.001**
Hypercholesterolemia				
No	14.9	**Referent**		
Yes	31.2	2.59	1.46 - 4.60	**0.001**
Hypertriglyceridemia				
No	20.6	**Referent**		
Yes	38.0	2.37	1.24 - 4.53	**0.009**

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

Independent variables were taken from the baseline study. O.R: Odds Ratio. C.I: Confidence Interval. B.P: Blo Pressure. *1 serving = 80gm. $p < 0.05$ was considered significant.

3.3.2.2 Multiple logistic regression

Independent variables for modeling were chosen based on the findings from literature, significance in bivariate analysis and low multicollinearity among them. **'Forward Step wise Likelihood Ratio method'** was used for modeling. For each independent variable its strength of association with incident hypertension was given as odds ratio along with confidence interval after adjusting for other variables.

Table 3.8: Results of Multiple logistic regression: factors associated with incidence of hypertension

Risk factors	B	Adjusted O.R	95% C.I	p value
Age (years)				
15 - 34		**Referent**		
35 - 54	1.65	5.23	2.43 - 11.28	**< 0.001**
≥ 55	2.26	9.56	3.62 - 25.29	**< 0.001**
Smoking	0.90	2.46	1.04 - 05.80	**0.04**
High normal blood pressure	1.64	5.17	2.66 - 10.05	**< 0.001**
Abdominal obesity	1.17	3.23	1.59 - 06.55	**0.001**

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

Dependent variable: Incident hypertension. Other independent variables included in the model and found to be not significant were sex, alcohol use, physical activity, overweight, diabetes, hypercholesterolemia and hypertriglyceridemia. B: Beta co-efficient. O.R: Odds Ratio. C.I: Confidence Interval. Forward likelihood ratio method was used. $p < 0.05$ was considered significant. Model Nagelkerke R^2: 0.369 and Accuracy: 82.2%.

In the final model, higher age (≥ 35 years), smoking, high normal blood pressure and abdominal obesity were found to be independently associated with incident hypertension (Table 3.8). The model could explain 36.9 percent of the variation in the incidence of hypertension and it correctly classified 41.4 percent of respondents with incident hypertension.

3.4 Validation of the Indian Diabetes Risk Score (IDRS)

The diabetes identified by fasting blood sugar ≥ 126 mg percent and/or on anti-diabetic medications was used as the gold standard against which the risk score was validated. Since, the baseline fasting blood sugar values were available for all respondents; the score was validated on the baseline cohort. As the information on regular physical exercise and family history of diabetes were not available in the baseline study, they were collected in the present study and used for validation. The IDRS characteristics of respondents with diabetes and without were presented in Table 3.9. As expected, the respondents with diabetes were older, had higher waist circumference and higher fasting blood sugar than those without diabetes.

Table 3.9: IDRS characteristics of the respondents with diabetes versus no diabetes

Characteristics	**Diabetes**	**No diabetes***	**p value**
n	84	368	
Age (years)	50.5 ± 10.8	37.0 ± 13.8	**< 0.001**
Waist circumference (cm)	90.0 ± 10.9	81.8 ± 11.1	**< 0.001**
Strenuous work (%)	9.5	14.9	0.225
Regular exercise (%)	0	4.3	0.650
Family history of diabetes (%)			
One parent is diabetic	36.9	28.5	0.059
Both parents are diabetic	8.3	4.6	0.272
Fasting blood sugar (mg/dl)	184.6 ± 64.4	91.7 ± 13.2	**< 0.001**

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

*Includes both normoglycemia and impaired fasting glucose. Values are given as mean ± standard deviation unless otherwise specified. $p < 0.05$ was considered significant.

Table 3.10 shows the performance of IDRS in detecting respondents with likelihood of having diabetes. The overall prevalence of diabetes in the baseline study was 18.6 percent (95% C.I: 15.3-22.4 percent). The published cut-off value ≥ 60 had the optimum sensitivity of 85.7 percent (95% C.I: 76.7-91.6 percent), specificity of 59.2 percent (95% C.I: 54.2-64.1 percent) and positive likelihood ratio of 2.1 (95% C.I: 1.8-2.4).

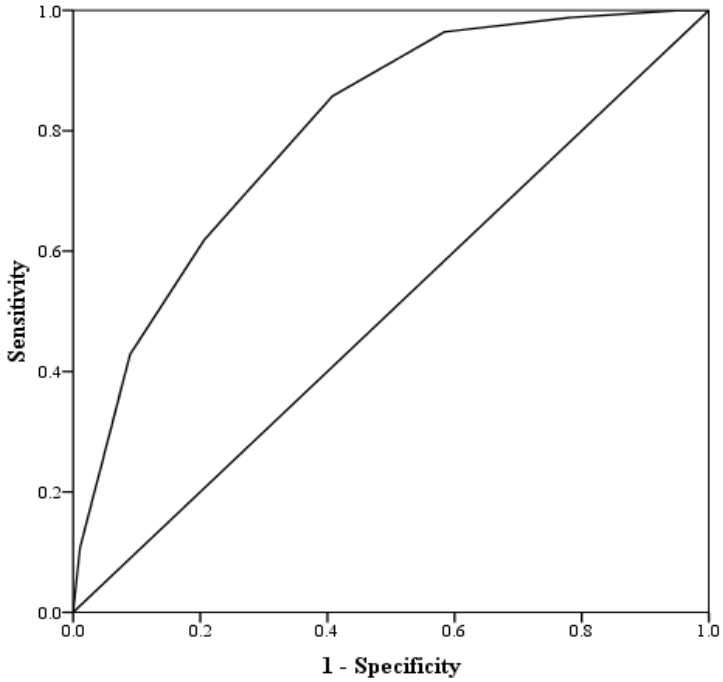
Table 3.10: Results of validation of the Indian Diabetes Risk Score (IDRS)

Cut-off value	Proportion of total subjects	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+ L.R	- L.R
≥ 10	100	100	0	18.6	0	1	0
≥ 20	100	100	0	18.6	0	1	0
≥ 30	96.2	100	4.6	19.3	100	1.05	0
≥ 40	82.1	98.8	21.7	22.4	98.8	1.26	0.06
≥ 50	65.5	96.4	41.6	27.4	98.1	1.65	0.09
≥ 60	**49.1**	**85.7**	**59.2**	**32.4**	**94.8**	**2.10**	**0.24**
≥ 70	28.3	61.9	79.3	40.6	90.1	2.99	0.48
≥ 80	15.3	42.9	91.0	52.2	87.5	4.77	0.63
≥ 90	2.9	10.7	98.9	69.2	82.9	9.73	0.90
≥ 100	0	0	100	0	81.4	0	1

Source: Primary survey, 2003 and 2010 Thiruvananthapuram.

Published cut off value was ≥ 60. PPV: Positive predictive value, NPV: Negative predictive value, L.R: Likelihood Ratio.

Figure 3.4: Receiver Operating Characteristic (ROC) curve showing the p Indian Diabetes Risk Score (IDRS)



The Area Under the Curve: 0.802 (95% C.I: 0.755 - 0.850) for the cut off value of ≥ 60 was significant ($p<0.001$) in detecting diabetes (Figure 3.4).

Chapter 4: Discussion

The present study showed a significant worsening of the cardiovascular risk factor profile of the rural cohort during a 6.5 year period. There was increase in the age adjusted prevalence of tobacco use, alcohol use, low fruit and vegetable intake, low physical activity, overweight, abdominal obesity and self reported diabetes along with a high incidence of hypertension. The age adjusted mean level of body mass index and waist circumference also increased. The Indian Diabetes Risk Score (IDRS) performed reasonably well in detecting diabetes.

Please Note: Literature for discussion was restricted mostly to the studies from India, Kerala and developing countries of the world.

4.1 Comparison of cardiovascular risk factors in the baseline and present study

To the best of my knowledge, there are no studies in India looking at the change in risk factors for cardiovascular diseases in a cohort. Hence, studies on temporal changes or time trends in cardiovascular risk factors were used for discussion.

4.1.1 Tobacco use

The increase in prevalence of tobacco use observed in the present study is alarming, given that smoking is causing large and growing number of deaths in India.[83] This increase is consistent with the available reports from India. Gupta et al, in Jaipur, reported an increase in the prevalence of smoking by 1.8 percent in men from 1995 to 2002.[84] Thankappan and Mini, by comparing NFHS-2 (1998-99) and NFH-3 data (2005-06) on tobacco use, showed that tobacco use in the rural areas of India increased from 47.4 percent to 61.8 percent during the seven year period.[85] On the other hand, tobacco use reduction was reported in other

developing countries of the world. Dowse et al, in Mauritius, reported a significant decline in the prevalence of cigarette smoking from 58.2 percent to 47.2 percent in men and from 6.9 percent to 3.7 percent in women during a five year period (1987-2002). They attributed the reduction to a national non-communicable disease intervention programme launched in 1987.[86] In Korea, tobacco control policies have resulted in 70 percent of the 24 percent reduction in the smoking rate between 1995 and 2006.[87]

In the present study, highest increase in the prevalence of smoking was found among young aged (15-24 yrs). This is in agreement with an earlier alarm raised by Reddy et al, about a new wave of tobacco use among young people in India.[88] The finding also reflects that, the age at initiation of smoking is below 25 years in Kerala.[89]

4.1.2 Alcohol use

In the scenario of higher risk for coronary heart disease associated with moderate to high alcohol intake among South Asians[90], increase in the prevalence of alcohol use observed in the present study gains utmost attention. The finding is in line with a recent report by Raekha Prasad on the rising alcohol use in India.[91] Similar situation was seen in other populations as well. In Russia, alcohol intake increased significantly in men and women during a 10 year period from 1992 to 2002.[92] There was a significant rise in the proportion of current drinking from 69.6 percent to 71.7 percent in men over a 41 year period in Japan.[93] However, alcohol use reduction was demonstrated in Mauritius following an effective intervention. The study showed a significant drop of 23.8 percent in men over a five year period.[86] To the contrast, the prevalence of alcohol drinking reduced from 52 percent to 39 percent during a 15 year period with no intervention, in Africa.[94]

The greatest increase in alcohol use among young aged (15-24 yrs) in the present study lends support to the finding, that the median age at initiation of alcohol use was found to be 21 year among people in the rural areas of Kerala.[95] Eventhough the proportion of alcohol use among women is low the increase was quite high in the present study. The reasons for this increase are not clearly evident.

4.1.3 Low fruit and vegetable intake

Sanjay et al, in their recent study reported that 75.5 percent of men and 68.4 percent of women in the rural areas of India have not met the recommended daily intake of fruits and vegetables.[96] This finding is in agreement with the present study, which showed that 73.1 percent of men and 60.3 percent of women consumed less than 400 gm of fruits and vegetables in a day.

The reduction in fruit and vegetable intake in the present study was against a claim by the WHO and FAO that, the consumption pattern of fruits and vegetables in India did not show much variation over years. They also reported that, the per capita intake of fruits and vegetables is from 120 to 140 gm per day in India.[38] The present study finding adds to the existing evidence on the changing agricultural pattern in Kerala from rice cultivation to cash crops.[97]

4.1.4 Physical activity

The significant increase in the level of physical inactivity observed in the present study is consistent with a study from North India. The study showed that, leisure time physical inactivity in women increased from 72.4 percent to 75.3 percent over a seven year period.[84] On the other hand, community empowerment through awareness programmes in two urban

colonies of Chennai has resulted in a significant rise in the proportion of high physical activity and decline in low physical activity over an 8 year period.[98] This kind of increase was also seen in Mauritius, where the prevalence of moderate leisure activity had an upsurge of 5.2 percent in men and 1.4 percent in women during a five year period.[84]

It is interesting to note that, shift in the level of physical activity between high to low among men in the present study confirmed a recently reported finding in Kerala.[99] There was not much change in occupation profile of the cohort in the present study. Hence, decline in the physical activity observed are presumed to be due to the life style changes, ageing and improvement in the socio-economic status (SES).

4.1.5 Blood pressure and Hypertension

In the present study, no significant difference in the mean level of blood pressure and proportion of hypertension was observed. This lends support to the finding seen in the urban areas of Jaipur. The study concluded that, probably a longer period is required to effect changes in the blood pressure in a given population.[100] However, it has been reported that the burden of hypertension is steadily increasing in India and other regions of the world. In rural areas of India it has raised from 0.5 percent in 1959 to 12.4 percent in 1994.[101] In China, a four percent upsurge in the prevalence of hypertension was found over a seven year period.[102] The MONICA study group in Nova Scotia reported that, the mean level of systolic blood pressure had an increase of 6.3 mmHg in men and 7.9 mmHg in women during a 10 year period.[103] On the other hand, there are success stories showing decrease in blood pressure level in the general population following activities pertaining to prevention. In North Karelia and other provinces of Finland, the mean level of blood pressure declined by

seven to nine mmHg among men and seven to 20 mmHg among women from 1972 to 1997 in response to a cardiovascular health intervention programme.[104] Similar trend was also found in Mauritius with the prevalence of hypertension dropping from 15 percent to 12.1 percent in men and from 12.4 percent to 10.9 percent in women following a non-communicable disease intervention programme.[86]

The cause for the slight downward trend in the prevalence of hypertension with no significant change in the blood pressure level is difficult to explain, given an increase in several other determinants of high blood pressure such as alcohol intake, low physical activity, body mass index, overweight, waist circumference and self reported diabetes in the present study. The probable explanation would be increase in the treatment and control rates of hypertension[94] and regression to mean among people with high values of blood pressure.[105]

4.1.6 Body mass index and Overweight

The upward trend in the mean level of body mass index and proportion of overweight seen in the present study is in line with two other Indian studies. Ramachandran et al, in rural Tamilnadu, reported an increase in the prevalence of overweight by 15.1 percent during a four year period.[106] Gupta et al, in an urban industrial population, have shown a steady increase in the body mass index level from 21.2 to 22.6 kg/m^2 over a five year period.[84] Similar change was also reported in other regions of the world.[94]

The increase in body mass index and proportion of overweight could be well explained by rise in the level of physical inactivity[107] and upsurge in the prevalence of low fruit and vegetable intake observed in the present study.[108]

4.1.7 Waist circumference and Abdominal obesity

The change in waist circumference and abdominal obesity was less frequently reported in the literature as compared to their highly correlated variable the body mass index and overweight respectively.

The high proportion of abdominal obesity in the present study is striking as waist circumference being an independent risk factor for diabetes.[79] The present study finding correlates well with the high burden of diabetes reported in the same population by Kutty et al.[99] The increase in mean waist circumference among men was higher than that of women in the present study. This is consistent with that reported by Ramachandran et al in rural Tamilnadu.[106] This observation could be because of the higher baseline mean level of waist circumference in women as compared to men.

4.1.8 Self reported diabetes

Increase in the prevalence of diabetes (self reported) observed in the present study adds to the growing evidence on raising burden of diabetes in India. Ramachandran et al, in rural south India, has shown a four fold rise in the prevalence of diabetes during a span of 14 years.[106] The same group, in urban Chennai, has shown a 40 percent rise between 1989 and 1995 and a further 16.4 percent increase during the next five years.[109,110] Mohan et al, by comparing four cross sectional surveys conducted in urban and rural areas of Chennai during the years 1989, 1995, 2000 and 2004 reported an upsurge in prevalence of diabetes by 72.3 percent.[111] Similar finding was also reported from northern India.[84] The increase in prevalence of diabetes could be well explained by rise in the proportion of overweight[79] and the mean level of waist circumference found in the present study[79].

4.2 Incidence of hypertension and the factors associated

4.2.1 Incidence of hypertension

Incidence of hypertension has been infrequently reported in India and other developing countries of the world. Cordeiro et al reported an incidence rate of 0.0964 $year^{-1}$ among tannery workers in Brazil.[112] A population based longitudinal study in urban Brazil has shown an incidence rate of 39 per 1000 person-years.[113] In India, incidence of hypertension was first reported by Gopinath et al in 1994 from an urban population in New Delhi. They reported an annual cumulative incidence of 12.2 per 1000 using cut off values 160 mmHg for systolic blood pressure and 90 mmHg for diastolic blood pressure.[114] In the present study, incidence rate among pre-hypertensives was 59 per 1000 person-years which is quite similar to that reported in the TROPHY study.[115]

4.2.2 Factors associated with Incident hypertension

In the present study, age, smoking, high normal blood pressure and abdominal obesity were found to be independently associated with incident hypertension.

4.2.2.1 Smoking and Incident hypertension

Strikingly, smoking turned out be an independent risk factor for incident hypertension in the present study. This is contrary to that found in other studies on the association between smoking and risk of hypertension. Two studies in the rural areas of Kerala showed odds ratios of 0.56 and 0.75 for tobacco users as compared to non-users for the risk of having hypertension.[116,72] These were cross sectional studies and their limitation in establishing association should be considered. The relationship between smoking and risk of hypertension

was found to be not consistent in studies from different regions of the world. In the Strong Heart Study, the mean level of systolic blood pressure was found to be negatively associated with smoking.[117] In Korea, it was shown that cessation of smoking increases the risk of developing hypertension.[118] In Japan, blood pressure among current smokers were found to be lower than that of ex and non-smokers.[119] On the other hand, data suggesting a positive relationship between smoking and risk of hypertension are limited. A study which analyzed data from the annual Health Survey for England showed a weaker association between current smoking and high systolic blood pressure in older men after adjusting for other confounding factors.[120] Surprisingly, the so called "hypertension paradox" was not observed in the present study, instead an inverse relationship was found. Further large scale longitudinal studies are required to clarify on the association between smoking and risk of hypertension.

4.2.2.2 High normal blood pressure and Incident hypertension

In the present study, high normal blood pressure had a strong association (O.R: 5.17) with the risk of hypertension. This finding gains attention, given that high normal blood pressure is an independent risk factor for cardiovascular disease.[43] The relationship between high normal blood pressure and risk of hypertension was first reported in the Framingham Heart study. In 1990, the study showed a relative risk of 2.25 in men and 1.89 in women for the development of hypertension.[121] Subsequently in 2001, it showed that the progression rate to hypertension during a four year period was higher for individuals with high normal blood pressure (37.3 percent) than those with normal blood pressure (17.6 percent).[122] This relationship was consistent in The Trial of Preventing Hypertension (TROPHY) study.[115]

4.2.2.3 Abdominal obesity and Incident hypertension

In the present study, abdominal obesity was independently associated with the risk of hypertension. The positive association between higher waist circumference and risk of hypertension has long been recognized. However, the cutoff level used for defining abdominal obesity in these populations was higher than that used in the present study.[123,124,125] The finding in the present study is similar to that seen with the risk of diabetes and cardiovascular diseases among Asian population as compared to the people of western origin.[126]

4.3 Validation of The Indian Diabetes Risk Score (IDRS)

The risk score performed reasonably well as compared to its original evaluation. The published cut off value (≥ 60) had a higher sensitivity (85.7 percent) and Area Under the Curve (80.2 percent) with similar specificity (59.1 percent).[66] The Area Under the Curve value was also higher than that reported for two other risk scores developed in India.[70,71] A recent study from rural Tamilnadu used IDRS for identifying people at high risk for having diabetes. However, it did not validate IDRS rather it used the score as a screening tool.[127]

According to Mohan et al, IDRS can be used for selective screening instead of universal screening. The screening could be performed in two steps, first being the application of IDRS followed by fasting blood sugar testing on those with risk score ≥ 60 (49.1 percent in this study sample). This would detect almost 86 percent of people with diabetes thereby making the screening to be cost effective.

4.4 Strengths of the study

- The study is a community based cohort study.
- High response rate (98.7%).
- To the best of my knowledge, first study in India looking at the changes in cardiovascular risk factors in a rural cohort.
- All physical measurements were taken by a single observer thereby avoiding observer bias.

4.5 Limitations of the study

- The study might lack statistical power to establish longitudinal association between variables due to its sampling method; hence measure of association was not presented as relative risk.
- Information on fruit and vegetable intake and physical activity were self reported. This calls for cautious interpretation of change in these measures over the time period.
- For validation of the diabetes risk score, information on regular exercise and family history of diabetes were obtained prospectively which might have influenced its performance.

4.6 Conclusion

The findings of the present study drive utmost attention among the researchers and policy makers in India. The increase in burden of major cardiovascular risk factors with a high incidence of hypertension documented in the present study is indicative of future cardiovascular disease outbreak in this population. The study also adds to the existing evidence on the younger age of escalation of risk factors for cardiovascular diseases in our country. Lack of public health response to this kind of situation will result in a catastrophic ending. Hence, there is an urgent need for translating the research in to action in India.

4.7 Policy implications

1. The findings of the present study warrants effective population and individual level strategies to reduce the major cardiovascular risk factors such as tobacco use, alcohol use, low fruit and vegetable intake, physical inactivity, overweight, abdominal obesity and diabetes in this rural population.

2. The interventions should provide a special focus on the following:

- The young aged should be targeted for tobacco and alcohol use cessation.
- The surrounding environment should be made conducive for promoting physical activity.
- The individuals with high normal blood pressure should be frequently monitored and preventive measures must be adopted to prevent them from developing hypertension.

3. The Indian Diabetes Risk Score could make mass screening programmes for diabetes cost effective as it requires only 50 percent of the individuals in a population to be tested with fasting blood sugar.

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Appendix I

Informed consent form from the principal investigator of the baseline study

To
Address of the Participant

Dear _____

Thanks for your participation in the study conducted by Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology during 2003-05 to detect the level of various non-communicable disease risk factors in your community. We wish to conduct a follow-up study among 495 participants of the previous study who have undergone blood tests for blood sugar and cholesterol to assess the change in risk factor levels over these last five to seven years. My student Dr.T.Sathish from our institution will be conducting this study as part of his Master of Public Health course. We hope that you will agree to participate in this study and also extend your cooperation to Dr.Sathish. I request your consent for sharing your contact details and other information collected with Dr.Sathish. If you provide consent, Dr.Sathish will have access to your old clinical investigation data. It is purely voluntary which means that you can decide whether to give consent or not. Dr.Sathish will be collecting data from the consented individuals during 16th June to 15th September 2010.

Thanking you

Yours truly

Dr.K.R.Thankappan
Principal Investigator of the 2003-2005 study,
Professor and Head,
Achutha Menon Centre for Health Science Studies,
Sree Chitra Tirunal Institute for Medical Sciences and Technology,
Thiruvananthapuram - 11, Kerala.

Consent

I consent

Signature/Thumb impression:

Name and Date:

I do not consent

Signature/Thumb impression:

Name and Date:

Appendix II
Research Subject Information Sheet

I am Dr.T.Sathish, a Master of Public Health (MPH) scholar from Achutha Menon Center for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram currently undertaking a study ***"Change in Cardiovascular Risk Factor Profile of a Rural Cohort in Thiruvananthapuram district, Kerala".*** It is being carried out as part of my course requirement. The consent requested is for this study. This research subject information sheet may contain words that you do not understand. Please ask me if any word or information is not clearly understood by you.

Purpose of the Study

Diabetes, hypertension, obesity, physical inactivity, unhealthy eating habits, use of tobacco and alcohol are the common risk factors for various cardiovascular diseases like heart attack, heart failure and stroke. A survey was carried out among randomly selected individuals in Venganoor panchayat of the Athiyannoor block by Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology during 2003 to 2005. In that survey, you were asked questions relating to your diet, physical activity, and other habits. In addition, blood samples were collected for testing blood sugar and cholesterol. As one of the original participants of the 2003-05 study, you are being approached now, to help us detect the changes in cardiovascular risk factors over the period of last five to seven years. The clinical data collected from you during 2003 to 2005 will be used in this study.

Procedure

The survey would take approximately 30 to 45 minutes of your valuable time. You will be asked questions relating to your diet, physical activity, and other habits in addition blood pressure (B.P), weight and waist circumference will be taken. The data collected will be used for research purposes only. I may contact you again if the collected information is found to be incomplete.

Risks and Discomforts

Participation in this study imposes no risk to your health. However you would be asked questions which you may find personal in nature.

Benefits

There may not be any direct benefit for you from this study. The information collected from you and other participants will be helpful in understanding the trend in levels of cardiovascular risk factors in this community.

Confidentiality

You will be interviewed and physical measurements will be taken in a private area in your household. All information related to you will be kept confidential in a safe keeping and at no stage will your identity be revealed. Each participant will be given an identification number (ID) which will help in maintaining the confidentiality of the data collected. Principal investigator of the study will alone have access to the data collected.

Contact Information

If you have any research related questions or you would like to verify my credentials, you may contact me or a member of our institute's Ethics Committee at the following address:

Dr.T.Sathish
MPH 2009
AMCHSS, SCTIMST
Thiruvananthapuram - 11
Mobile: 9746443985

Dr.Anoop Kumar Thekkuveettil
Member Secretary
Institutional Ethics Committee (I.E.C)
SCTIMST, Thiruvananthapuram - 11
Office: 0471 - 2520256/2520257

Voluntary participation

Your participation in this study is purely voluntary which means you can decide whether to participate in the study or not. If at any stage you wish to discontinue, you are free to do so without any adverse consequences.

Appendix III

Informed consent form for the present study

Change in Cardiovascular Risk Factor Profile of a Rural Cohort in Thiruvananthapuram District, Kerala

Achutha Menon Center for Health Science Studies,

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram - 11

CONSENT FORM

I have read / been read out the information in the Research subject information sheet. The nature of the study and my involvement has been explained and all my questions have been answered satisfactorily. By signing this consent form, I indicate that I understand what will be expected from me and I am willing to participate in this study. I know that I can withdraw at any time. I have been informed who should be contacted if the need arises.

Respondent's Signature / Thumb Impression:

Date:

Interviewer's Name:

Interviewer's Signature:

Date:

Appendix V

THE INDIAN DIABETES RISK SCORE (IDRS)

Mohan V, Deepa R, Deepa M, Somannavar S, Datta M. A Simplified Indian Diabetes Risk Score for Screening for Undiagnosed Diabetic Subjects. *JAPI* 2005; 53: 759-63.

Particulars	Score
Age	
<35 [reference]	0
35-49	20
≥50	30
Abdominal obesity	
Waist <80 cm [female], 90 [male] [reference]	0
Waist ≥80 - 89 cm [female], ≥90 - 99 cm [male]	10
Waist ≥90 cm [female], ≥100 cm [male]	20
Physical activity	
Exercise [regular] + strenuous work [reference]	0
Exercise [regular] or strenuous work	20
No exercise and sedentary work	30
Family history	
No family history [reference]	0
Either parent	10
Both parents	20
Minimum score	0
Maximum score	100
Published cutoff value	≥ 60

Appendix VI
Physical activity categorization chart

Equation:

Total physical activity MET-minutes per week = [(P2*P3*8) + (P5*P6*4) + (P8*P9*4) + (P11*P12*8) + (P14*P15*4)].

Levels of physical activity and cutoff values:

High

- IF: (P2 +P11) ≥ 3 days AND Total physical activity MET minutes per week is ≥ 1500.

OR

- IF: (P2 + P5 + P8 + P11 + P14) ≥ 7 days AND total physical activity MET minutes per week is ≥ 300.

Moderate

- IF: level of physical activity does not reach criteria for higher levels of physical activity.

AND at least one of the following

- IF: (P2 +P11) ≥ 3 days AND ((P2*P3) + (P11*P12)) ≥ 3*20 minutes.

OR

- IF: (P5 +P8 + P14) ≥ 5 days AND ((P5*P6) + (P8*P9) + (P14*P15)) ≥ 150 minutes.

OR

- IF: (P2 + P5 + P8 + P11 + P14) ≥ 5 days AND Total physical activity MET minutes per week ≥ 600.

Low: IF the level of physical activity does not reach the criteria for either high or moderate levels of physical activity.

Source: WHO STEPwise approach surveillance manual.[73]

Appendix VII
Steps in taking physical measurements
Measuring Blood pressure

Applying the cuff

1. Place the right arm of the participant on the table with the palm facing upward.

2. Remove or roll up clothing on the arm.

3. Select the appropriate cuff size for the participant using the following table:

Arm circumference (cm)	**Cuff size**
17-22	Small (S)
22-32	Medium (M)
> 32	Large (L)

4. Position the cuff above the elbow aligning the mark ART on the cuff with the brachial artery.

5. Wrap the cuff snugly on to the arm and securely fasten with the Velcro.

Note: The lower edge of the cuff should be placed 1.2 to 2.5 cm above the inner side of the elbow joint.

6. Keep the level of the cuff at the same level as the heart during measurement.

Taking the measurement

1. Switch the monitor on and press START.

2. The monitor will start measuring when it detects the pulse and the "heart" symbol will begin to flash. The systolic and diastolic blood pressure readings should be displayed within a few moments.

3. Record the reading in the participant's instrument.

4. Switch the monitor off, but leave the cuff in place.

Source: WHO STEPwise approach surveillance manual.[73]

Measuring Height

1. Ask the participant to remove their:

- foot wear (shoes, slippers, sandals, etc)
- head gear (hat, cap, hair bows, comb, ribbons, etc)

2. Ask the participant to stand with:

- feet together
- heels against the back board
- knees straight

3. Ask the participant to look straight ahead and not tilt their head up.
4. Make sure eyes are the same level as the ears.
5. Ask the participant to breathe in and stand tall.
6. Read the height in centimeters at the exact point.
7. Record the height measurement in centimeters in the participant's instrument.

Measuring Weight

1. Put the scale on a firm, flat surface.
2. Ask the participant to remove their footwear (shoes, slippers, sandals, etc) and socks.
3. Ask the participant to step on to scale with one foot on each side of the scale.
4. Ask the participant to:

- Stand still
- Face forward
- Place arms on the side and
- Wait until asked to step off

5. Record the weight in kilograms on the participant's instrument

Source: WHO STEPwise approach surveillance manual.[73]

Measuring Waist circumference

1. Standing to the side of the participant, locate the last palpable rib and the top of the hip bone. You may ask the participant to assist you in locating these points on their body.

2. Ask the participant to wrap the tension tape around themselves and then position the tape at the midpoint of the last palpable rib and the top of the hip bone, making sure to wrap the tape over the same spot on the opposite side.

Note: Check that the tape is horizontal across the back and front of the participant and as parallel with the floor as possible.

3. Ask the participant to:

- Stand with their feet together with weight evenly distributed across both feet
- Hold the arms in a relaxed position at the sides
- Breathe normally for a few breaths, then make a normal expiration

4. Measure waist circumference and read the measurement at the level of the tape to the nearest 0.1 cm, making sure to keep the measuring tape snug but not tight enough to cause compression of the skin.

5. Record the measurement on the participant's instrument.

Source: WHO STEPwise approach surveillance manual.[73]

Appendix IV: Interview Schedule

Survey Information

Location and Date		Response	Code
1	Respondent identification number (ID)	⌊_⌊_⌊_⌊_⌋	I1
2	Ward number	⌊_⌊_⌋	I2
3	Date of completion of the instrument	⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋ dd mm year	I3

If the participant has expired, please elicit answer to only question 51 and end the interview.

Step 1 Demographic Information

CORE: Demographic Information			
Question		**Response**	**Code**
4	In total, how many years have you spent at school or in full-time study (excluding pre-school)?	Years of schooling ⌊_⌊_⌋	C1
5	Which of the following best describes your <u>main</u> work status over the last 12 months?	Professional/Executive/ Big business 1 Clerical/ medium business 2 Self-employed/skilled 3 Unskilled/landless labourer 4 Student 5 Homemaker/House wife 6 Retired 7 Unemployed (able to work) 8 Unemployed (unable to work) 9 Other (specify) 10 …….. Refused 88	C2
6	What is the highest level of education you have completed?	No formal schooling 1 Less than primary school 2 Primary school completed 3 Secondary school completed 4 High school completed 5 Plus 2/ Pre degree 6 Graduation 7 Post graduation 8 Technical 9 Professional 10 Other (specify) 11 …….. Refused 88	C3

Respondent ID ⌊_⌊_⌊_⌊_⌋

Step 1 Behavioural Measurements

CORE: Tobacco Use (Section T)			
Question		**Response**	**Code**
7	Do you currently smoke any **tobacco products**, such as cigarettes, beedi, hukka, cigars? (in last 30 days)	Yes 1 No 2 *If No, go to T6*	T1
8	Do you currently smoke tobacco products **daily**?	Yes 1 No 2 *If No, go to T6*	T2
9	How old were you when you **first started** smoking daily?	Age (years) ⌊_⌊_⌋ *If Known, go to T5a* Don't remember 77	T3
10	Do you remember how long ago it was? *(Code 77 for Don't know or Don't remember)*	In Years ⌊_⌊_⌋	T4a
		or in Months ⌊_⌊_⌋	T4b
		or in Weeks ⌊_⌊_⌋	T4c
11	On average, **how many** of the following do you smoke each day? *(Record for each type)* *(Code 77 for Don't know)* *(Code 88 for Not applicable)*	Manufactured cigarettes ⌊_⌊_⌋	T5a
		Beedi ⌊_⌊_⌋	T5b
		Pipes full of tobacco/hukka ⌊_⌊_⌋	T5c
		Cigars ⌊_⌊_⌋	T5d
		Other (please specify) …….. ⌊_⌊_⌋	T5e
12	Do you **currently use** any **smokeless tobacco** such as [*snuff, chewing tobacco, betel, ghutka, kahaini, or other]*?	Yes 1 No 2 *If No, go to A1a*	T6
13	Do you **currently use smokeless tobacco** products **daily?** (in last 30 days)	Yes 1 No 2 *If No, go to A1a*	T7
14	On average, how many **times a day** do you use *(RECORD FOR EACH TYPE)* (Code 77 for Don't know) (Code 88 for Not applicable)	Snuff ⌊_⌊_⌋ Ghutka ⌊_⌊_⌋ Kahaini ⌊_⌊_⌋ Chewing tobacco alone ⌊_⌊_⌋ Betel alone ⌊_⌊_⌋ Chewing tobacco and Betel ⌊_⌊_⌋ Other (please specify) ……..... ⌊_⌊_⌋	T8

Respondent ID ⌊_⌊_⌊_⌊_⌋

CORE: Alcohol Consumption (Section A)			
Question		**Response**	**Code**
15	Have you **ever** consumed a drink that contains alcohol such as beer, whisky, rum, gin, brandy, or other local products?	Yes 1 No 2 *If No, go to D1*	A1a
16	Have you consumed alcohol within the **past 12 months**?	Yes 1 No 2 *If No, go to D1*	A1b
17	In the past 12 months, **how frequently** have you had at least one drink? *(READ RESPONSES)*	5 or more days a week 1 1-4 days per week 2 1-3 days per month 3 Less than once a month 4	A2
18	When you drink alcohol, **on average**, how many drinks do you have during one day?	Number ⌊_⌊_⌋ Don't know 77 ⌊_⌊_⌋	A3
19	During each of the **past 7 days**, how many standard drinks of any alcoholic drink did you have each day? *(RECORD FOR EACH DAY)* *(Code 77 for Don't know)*	Monday ⌊_⌊_⌋ Tuesday ⌊_⌊_⌋ Wednesday ⌊_⌊_⌋ Thursday ⌊_⌊_⌋ Friday ⌊_⌊_⌋ Saturday ⌊_⌊_⌋ Sunday ⌊_⌊_⌋	A4

CORE: Diet (Section D)			
Question		**Response**	**Code**
20	In a typical week, on how many days do you **eat fruit**?	Number of days ⌊_⌊_⌋ *If Zero days, go to D3*	D1
21	How many **servings** of fruit do you eat on **one** of those days?	Number of servings ⌊_⌊_⌋	D2
22	In a typical week, on how many days do you **eat vegetables**?	Number of days ⌊_⌊_⌋ *If Zero days, go to P1*	D3
23	How many **servings** of vegetables do you eat on one of those days?	Number of servings ⌊_⌊_⌋	D4
24	What type of **oil or fat is most often** used for meal preparation in your household? *(SELECT ONLY ONE)* *(Code 77 for Don't know)*	Vegetable oil (refined/unhydrogenated) 01 Vegetable oil (hydrogenated) 02 Butter or ghee 03 Other (please specify) 04 …… None in particular 05 Cocunut oil 06 ⌊_⌊_⌋	D5

Respondent ID ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

CORE: Physical Activity (Section P)			
Question		**Response**	**Code**
Work			
25	Does your work involve mostly sitting or standing, with walking for no more than 10 minutes at a time?	Yes 1 No 2 *If No, go to P 6*	P1
26	Does your work involve vigorous activity, like [*heavy lifting, digging or other work*] for at least 10 minutes at a time?	Yes 1 No 2 *If No, go to P 4*	P2
27	In a typical week, on how many days do you do vigorous activities as part of your work?	Days a week ⌊_⌋⌊_⌋	P3a
28	On a typical day on which you do vigorous activity, how much time do you spend doing such work?	In hours and minutes hrs ⌊_⌋⌊_⌋ : mins ⌊_⌋⌊_⌋ Or in Minutes only mins ⌊_⌋⌊_⌋⌊_⌋	P3b
29	Does your work involve moderate-intensity activity, like brisk walking *[or carrying light loads*] for at least 10 minutes at a time?	Yes 1 No 2 *If No go to p6*	P4
30	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Days a week ⌊_⌋⌊_⌋	P5a
31	On a typical day on which you did moderate-intensity activities, how much time do you spend doing such work?	In hours and minutes hrs ⌊_⌋⌊_⌋ : mins ⌊_⌋⌊_⌋ or in Minutes only mins ⌊_⌋⌊_⌋⌊_⌋	P5b
32	How long is your typical workday?	Number of hours hrs ⌊_⌋⌊_⌋	P6
Travel to and from places			
33	Do you walk or use a bicycle *(pedal cycle)* for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 *If No, go to P 9*	P7
34	In a typical week, on how many days do you walk or bicycle for at least 10 minutes to get to and from places?	Days a week ⌊_⌋⌊_⌋	P8a

35	How much time do you spend walking or bicycling for travel on a typical day?	In hours and minutes hrs └┴┘ : mins └┴┘ or in Minutes only mins └┴┘	P8b
Recreational activities			
36	Does your [*recreation, sport or leisure time*] involve mostly sitting, reclining, or standing, with no physical activity lasting more than 10 minutes at a time?	Yes 1 No 2 *If Yes, go to P14*	P9
37	In your [*leisure time*], do you do any vigorous activities like [*running or strenuous sports, weight lifting*] for at least 10 minutes at a time?	Yes 1 No 2 *If No, go to P12*	P10
38	In a typical week, on how many days do you do vigorous activities as part of your [*leisure time*]?	Days a week └┴┘	P11a
39	How much time do you spend doing this on a typical day?	In hours and minutes hrs └┴┘ : mins └┴┘ or in minutes only └┴┘	P11b
40	In your [*leisure time*], do you do any moderate-intensity activities like [brisk walking*, cycling or swimming*] for at least 10 minutes at a time?	Yes 1 No 2 *If No, go to P14*	P12
41	In a typical week, on how many days do you do moderate-intensity activities as part of [*leisure time*]?	Days a week └┴┘	P13a
42	How much time do you spend doing this on a typical day?	In hours and minutes hrs └┴┘ : mins └┴┘ or in Minutes only mins └┴┘	P13b
43	Do you exercise regularly?	Yes 1 No 2	P14

CORE: Diabetes and Hypertension			
Question		**Response**	**Code**
44	When was your blood pressure last measured by a health professional?	Within past 12 months 1 1-6 years ago 2 Not within past 5 years 3	H1
45	During the past 12 months have you been told by a doctor or other health worker that you have elevated blood pressure or hypertension?	Yes 1 No 2 *If No, go to H4*	H2
46	Are you currently receiving any treatment for high blood pressure prescribed by a doctor or other health worker?	Yes 1 No 2	H3
47	Have any of the members of your immediate family or other relatives been diagnosed with hypertension? *(tick all that is applicable)*	Mother 1 Father 2 Brother 3 Sister 4 Son 5 Daughter 6 None 7 Other (Please specify) ……	H4
48	Have you had your blood sugar measured in the last 12 months?	Yes 1 No 2	H5
49	Have you ever been told by a doctor or other health worker that you have diabetes?	Yes 1 No 2 *If No, go to H8*	H6
50	Are you currently receiving any treatment for diabetes prescribed by a doctor or other health worker?	Yes 1 No 2	H7
51	Have any of the members of your/his/her immediate family or other relatives been diagnosed with diabetes? *(elicit from family members or relatives if the participant has expired)* *(tick all that is applicable)*	Mother 1 Father 2 Brother 3 Sister 4 Son 5 Daughter 6 None 7 Other (Please specify) ……	H8

Respondent ID ⌊_⌊_⌊_⌊_⌋

Step 2 Physical Measurements

Question		Response	Code
Weight			
52	Weight *If too large for scale 666.6*	in Kilograms (kg) ⌊_⌊_⌊_⌋.⌊_⌋	M1
Waist			
53	Waist circumference	in Centimetres (cm) ⌊_⌊_⌊_⌋.⌊_⌋	M2
Blood Pressure			
54	Cuff size used	Small 1 Medium 2 Large 3	M3
55	Reading 1	Systolic (mmHg) ⌊_⌊_⌊_⌋	M4a
		Diastolic (mmHg) ⌊_⌊_⌊_⌋	M4b
56	Reading 2	Systolic (mmHg) ⌊_⌊_⌊_⌋	M5a
		Diastolic (mmHg) ⌊_⌊_⌊_⌋	M5b
57	Reading 3	Systolic (mmHg) ⌊_⌊_⌊_⌋	M6a
		Diastolic (mmHg) ⌊_⌊_⌊_⌋	M6b