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Original Article

Prevalence of coronary artery disease and coronary risk factors in Kerala, South India: A population survey – Design and methods

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ABSTRACT

Background: There is paucity of reliable contemporary data on prevalence of coronary artery disease (CAD) and risk factors in Indians. Only a few studies on prevalence of CAD have been conducted in Kerala, a Southern Indian state. The main objective of the Cardiological Society of India Kerala Chapter Coronary Artery Disease and Its Risk Factors Prevalence Study (CSI Kerala CRP Study) was to determine the prevalence of CAD and risk factors of CAD in men and women aged 20–79 years in urban and rural settings of three geographical areas of Kerala.

Methods: The design of the study was cross-sectional population survey. We estimated the sample size based on an anticipated prevalence of 7.4% of CAD for rural and 11% for urban Kerala. The derived sample sizes for rural and urban areas were 3000 and 2400, respectively. The urban areas for sampling constituted one ward each from three municipal corporations at different parts of the state. The rural sample was drawn from two panchayats each in the same districts as the urban sample. One adult from each household in the age group of 20–59 years was selected using Kish method. All subjects between 60 and 79 years were included from each household. A detailed questionnaire was administered to assess the risk factors, history of CAD, family history, educational status, socioeconomic status, dietary habits, physical activity and treatment for CAD; anthropometric measurements, blood pressure, electrocardiogram and fasting blood levels of glucose and lipids were recorded.

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1. Background

Coronary artery disease (CAD) affects millions of people the world over. Studies from the United States of America and elsewhere have established CAD as a leading cause of morbidity and death. The prevalence of CAD among adults in the USA in 2005 was 7.3%.[1] It is estimated that migrant Asians have the highest prevalence of CAD in the world.[2–4] However, there is paucity of reliable contemporary data on prevalence of CAD and risk factors in native Indians.

Various studies from India have shown high prevalence of the disease, approaching approximately 11% in the urban population and 7% in the rural population across India.[5–15] In a systematic review of 27 prevalence studies from India, Ahamed et al noted that many of the studies did not meet the basic requirements of epidemiologic research and most studies were from Delhi or surrounding areas.[16] An urban survey by Mohan et al from Chennai, South India reported a prevalence rate of 11% in 2001.[17] Only a few studies on prevalence of CAD have been conducted in Kerala, a Southern Indian state. A study by Kutty et al in 1993 in a Southern rural area of Kerala reported a CAD prevalence rate of 7.4%.[18] There have been no major studies on prevalence of CAD in Kerala since then; nor are there any prevalence studies from rest of the state. It cannot be assumed that figures from the Southernmost region of Kerala are applicable to rest of the state.

The huge burden of CAD in India is the consequence of a large population as well as high prevalence rate of CAD risk factors. A case-control study of risk factors for CAD (the INTERHEART Study) including a considerable number of participants from India showed the importance of conventional risk factors in the causation of CAD.[19] There has been an explosion in the prevalence of traditional risk factors of CAD in India, largely driven by the rapid increase in the proportion of urban inhabitants. Urbanization has resulted in development of dysglycemia, hypertension, dyslipidemia and metabolic syndrome, providing necessary milieu for rising incidence of CAD. The recently published study in urban, rural and slum settings in Thiruvananthapuram showed a high prevalence of CAD risk factors.[20]

The main objective of the Cardiological Society of India Kerala Chapter Coronary Artery Disease and Its Risk Factors Prevalence Study (CSI Kerala CRP Study) was to determine the prevalence of CAD and risk factors of CAD in men and women aged 20–79 years in urban and rural settings of three geographical areas of Kerala.

2. Design and methods

The design of the study was cross-sectional population survey.

2.1. Determination of sample size

We estimated the sample size based on an anticipated prevalence of 7.4% of CAD for rural Kerala based on the data by Kutty et al[18] and 11% for urban Kerala based on the study by Mohan et al in Chennai.[17] The lowest acceptable prevalence was considered as 6.08% (95% confidence interval 6.08–8.78%) for rural Kerala and 9.2% (95% confidence interval 9.2–12.8%) for urban Kerala. Since the sample selection was closer to cluster sampling, a design effect of 2 was also considered for arriving at the final sample size. The level of confidence was taken as 1.96 which was the probability value associated with 95% confidence interval. The level of precision used in the rural area was 1.35% and that for urban area was 1.8%.

The total sample size (n) was estimated using the formula, $n = Z^2 P (1-P)/e^2$ where Z was the level of confidence, P was the anticipated prevalence and e was the level of precision. The derived sample sizes for rural and urban areas were 3000 and 2400 respectively.

2.2. Sample selection procedure

Subjects of the study were adults between the ages 20–79 years who were permanent residents of the areas of sampling. Electoral rolls updated in 2010 for the respective electoral wards were taken as the basic documents for selection of participants. Errors in the electoral rolls were corrected by volunteers after visiting each household.

2.3. Urban area

Kerala, the southernmost state of India (Area 38360 sq. km) has 14 districts with a total population of 33.39 million as per 2011 census. The urban administrative units are municipal corporations. We chose one municipal corporation each from the southern, central and northern districts for the survey to ensure equitable geographic distribution (Fig. 1).

Each municipal corporation is divided into electoral wards. The southern Thiruvananthapuram municipal corporation has 100 wards, central Thrissur municipal corporation 55 wards and northern Kozhikode municipal corporation 75 wards. One of the wards from each of the corporations was randomly selected. Thus, three randomly selected wards from the three major cities of Kerala constituted the urban area for this study. The areas of sampling and the population statistics is given in Table 1.

We divided each of the selected wards into three to six geographical units and randomly selected one of these units. From the selected unit all the households were included in the survey. Using the updated voters' list, each household was numbered serially (Household Index Number – HIN). A list of all the eligible participants was constructed, men and women separate, from each household with separate columns for those at or above 60 years and for those between 20 and 59 years of age. One adult from each household in the age group of 20–59 years was selected using Kish method (WHO STEPS Manual[21]) to ensure representation of the age-sex distribution of the population. Briefly the Kish method was as follows: a list of participants between 20 and 59 years was constructed in the descending order of age, first for males and then for females in each household. Random selection of one subject from each household was done using Kish table. All subjects between 60 and 79 years were included in the sample to ensure sufficient number of subjects in the older age group in

Fig. 1 – Map of Kerala state showing the various districts and urban sampling areas (arrows).

Table 1 – The area of sampling and population statistics of the urban sample.

Municipal corporation	Population between ages 20 and 79 in the municipal corporation	Ward no	Population between ages 20 and 79 in the ward	Sample
Thiruvananthapuram	653916	17	9985	877
Thrissur	315596	38	5530	826
Kozhikode	283842	67	7231	999

the final sample. Each participant in either group was given unique Participant Index Number (PIN) serially.

2.4. *Rural area*

Rural area of Kerala is divided into panchayats consisting of approximately 10–15 administrative units called wards. Thiruvananthapuram, Thrissur and Kozhikode districts have 73, 88 and 75 panchayats, respectively. Two panchayats each were randomly selected from each of the above districts. From the selected panchayats one ward each was selected randomly. Thus six panchayat wards in Kerala constituted the rural area of this study. The area of sampling and the population statistics for rural survey is given in Table 2.

From each of the selected wards all the households were included in the survey constituting approximately 500 subjects from each of the rural wards to make up a total of 3000 subjects. The method of sample selection was as followed for the urban sample.

3. Methods

The study was approved by the Ethics Committee of Cardiological Society of India, Kerala Chapter.

We sent a letter to all eligible subjects requesting participation. Each participant was invited to visit an easily accessible facility with all past medical records. Subjects were asked to report after overnight fasting. The survey included questionnaire, blood pressure (BP) measurements, anthropometric measurements, electrocardiogram and blood examinations. Nonresponders were personally visited at home and requested to participate.

3.1. *Investigators*

The team of investigators and the scheme of data collection included:

I. Principal investigator, who was a cardiologist trained in epidemiologic methods
II. A supervisor (nursing officer), who oversaw the proceedings
III. Trained nursing/medical students, who administered the questionnaire and performed the measurements
IV. Electrocardiogram taken by trained technicians
V. Blood sample collection performed by personnel from accredited laboratory.

The maximum number of participants evaluated in a day was limited to 70–80.

The investigating team was given prior training and instructions for proper collection and recording of data. Either the supervisor or the principal investigator verified each entry in the questionnaire and measurements on-site. The survey was conducted on Sundays simultaneously by separate team for each center. Urban center survey was targeted to be completed in 12 weeks and rural survey in 16 weeks. An informed consent was taken from each participant.

3.2. *Questionnaire*

We formulated a structured questionnaire in English language and translated it into the local language, Malayalam. Reverse translation was performed to ascertain the appropriateness of the conversion to local language. Data were collected using the standard interview method and responses were recorded. The subjects were queried on personal history of hypertension, dyslipidemia, diabetes mellitus and CAD. Questions were also administered concerning smoking, use of smokeless tobacco and alcohol. Dietetic history was taken with questions on intake of fruits and vegetables, fish and meat products and type of cooking oil. Questions concerning income, education and physical activity were included. Family history of ischemic heart disease, stroke and coronary risk factors was recorded. The instrument also contained the Rose Angina Questionnaire[22,23] and questions related to history of documented prior myocardial infarction (MI), unstable angina, coronary artery bypass graft (CABG) surgery, noninvasive investigations for CAD, coronary angiography, coronary angioplasty, documented use of drugs for CAD and hospital admission for CAD.

Table 2 – Area of sampling and population statistics of the rural sample.

District	Panchayat 1	Population	Ward no.	Population	Sample	Panchayat 2	Population	Ward no.	Population	Sample
Thiruvananthapuram	Karumkulam	27331	1	1178	456	Kanjiramkulam	18820	12	1245	524
Thrissur	Arimboor	25063	3	1900	795	Venkidangu	20574	3	1906	565
Kozhikode	Kakkur	16605	10	1162	520	Chelannur	27643	17	1704	915

3.3. Blood pressure

Blood pressure was recorded with electronic BP apparatus (model 1A2, Omron Corporation, Shimogyo-ku, Kyoto, Japan) in sitting position, on the left arm resting on a table at heart level, after the subject having rested for at least 15 min. Three readings were taken 3 min apart and the mean of the last two readings was recorded as the BP.[24] Heart rate was recorded in each case.

3.4. Anthropometric measurements

Height was measured by wall-mounted stadiometer (Model 206, Seca, Hamburg Germany) to the nearest centimeter. Subjects were asked to stand upright without shoes, with their back against the wall, heels together and eyes directed forward.

Weight was measured with portable electronic weighing scale (Model HN 283, Omron Corporation, Shimogyo-ku, Kyoto, Japan) kept on a firm horizontal surface. The subjects were asked to wear light clothing and remove footwear. Weight was recorded in kilograms to the nearest 0.5 interval. Body mass index was calculated as weight in kg/(height in meter).[2]

Waist circumference was measured using a non-stretchable fiber measuring tape. The subjects were asked to stand erect in a relaxed position with both feet together. Waist girth was measured at the midpoint between the iliac crest and the lower margin of the ribs at the end of expiration, to the nearest centimeter.

3.5. Electrocardiogram

Electrocardiograms were taken with 3 channel digital ECG recorders with facility for display and measured parameters. Resting 12 lead ECGs were performed on all subjects by trained technicians. For each lead, 5 consecutive complexes were recorded. All recorded ECGs were coded using Minnesota code[25] by a cardiologist. Ten percent of the coded ECGs were re-evaluated by another trained cardiologist for inter-observer variation.

3.6. Biochemical investigations

Blood samples were drawn from individuals after 10–12 h of fasting. Plasma glucose was estimated immediately, onsite using the Glucose oxidase/peroxidase- phenol-4-amenophenazone method (GOD-PAP). Blood samples for lipid profile measurement were transported on ice packs (4–6 °C) and thermocol boxes to a core accredited laboratory (Thyrocare Technologies Ltd, Navi Mumbai, India) on the same day. Estimation was carried out within 48 h in clinical chemistry instruments (Olympus AU2700) and Advia 1800 chemistry system (Siemens) using standard commercially available kits (Agappe Diagnostics). Photometry technology was used for lipid profile. Serum cholesterol was measured by cholesterol oxidase phenol-4-aminoantipyrine peroxidase (CHOD-PAP) method and serum triglycerides by glycerol-3-phosphate oxidase-p-aminophenazone peroxidase (GPO-PAP) method. HDL cholesterol was estimated by enzyme selective protection method. The reaction between cholesterol assay is suppressed by the electrostatic interaction between polyanions and cationic substances. Low density lipoprotein (LDL) cholesterol was calculated by using Friedwald's equation.

4. Definitions

4.1. Coronary artery disease

Coronary artery disease was diagnosed as follows:

1. **Definite CAD** based on *any of* the following:
   i. Documented evidence of prior acute coronary syndrome (ACS) or treatment for CAD
   ii. Documented history of undergoing coronary angioplasty or CABG
   iii. More than 50% epicardial coronary stenosis by invasive coronary angiography
   iv. ECG showing pathological Q waves (any of Minnesota code 1-1-1 to 1-1-7 or 1-2-1 to 1-2-5 or 1-2-7)
   v. Imaging evidence of a region of loss of viable myocardium that is thinned and has a motion abnormality, in the absence of a non-ischemic cause
   vi. Rose Angina Questionnaire (RAQ) angina *plus* ECG changes (any of Minnesota codes 4-1-1, 4-1-2, 4-2 or 5-l, 5-2)
   vii. Rose Angina Questionnaire angina *plus* positive treadmill ECG (exercise-induced horizontal or down- sloping ST depression of $\geq$ 1 mm at 80 ms from J point) or inducible ischemia on stress imaging
2. Probable CAD based on any of the following (in the absence of any of the definite criteria):
   i. Rose Angina Questionnaire angina without significant ECG changes
   ii. ECG changes (any of Minnesota Code 4-1-1,4-1-2, 4-2 *or* 5-1, 5-2) without RAQ angina
   iii. Positive treadmill ECG without RAQ angina
3. No CAD: absence of any of the criteria for definite or probable CAD
4. Any CAD: all those who have satisfied either definite or probable CAD criteria

Only cases with documentation of ACS or treatment for CAD were counted as positive for CAD. Participants were urged to produce treatment-related documents; those who could not produce documents of ACS or treatment for CAD were considered not having satisfied those CAD criteria. Rose Angina Questionnaire angina was taken as positive when all the first 8 questions for effort angina have been responded appropriately. All cases satisfying CAD criteria were checked by a different cardiologist as to the correctness of Minnesota coding and application of CAD criteria.

4.2. Diabetes mellitus

Diabetes mellitus (DM) was diagnosed if the fasting glucose value was $\geq$126 mg/dL and/or if there was current use of medications for diabetes. Those with fasting glucose $\geq$ 100 mg/dL but below 126 mg/dL and not currently on

antidiabetic medication were diagnosed as having impaired fasting glucose (IFG).

4.3. Hypertension

Normotensives were defined as subjects with systolic BP (SBP) <mmHg and diastolic BP (DBP) < 80 mmHg and not currently on antihypertensive medication. Subjects were considered to have hypertension if the BP was ≥140 mmHg systolic and/or ≥90 mmHg diastolic and/or currently on drugs for hypertension was reported. Prehypertension was defined as SBP > 120 but less than140 and/or DBP > 80 but less than 90 mmHg while not on antihypertensive medication.

4.4. Metabolic syndrome

Risk factor	Defining level
1. Abdominal obesity, given as waist circumference	
Men	>90 cm
Women	>80 cm
2. Triglycerides	≥150 mg/dL
3. HDL Cholesterol	
Men	<40 mg/dL
Women	<50 mg/dL
4. Blood Pressure	≥130/≥ 85 mmHg
5. Fasting Glucose	≥100 mg/dL

Metabolic syndrome was diagnosed by the Consensus Definition for Asian Indians.[26] Three or more of the following 5 risk factors if present was considered as diagnostic of metabolic syndrome.

Subjects with known diabetes and hypertension on treatment were included. They were deemed to have satisfied the fasting blood sugar and BP criteria even if their measured levels were lower.

4.5. Body mass index

Normal BMI was taken as 18.0–22.9 kg/m^2, overweight if BMI was between 23.0–24.9 kg/m^2, and obesity if BMI ≥ 25 kg/m^2 as per consensus statement.[26]

4.6. Dyslipidemia[27]

Dyslipidemia was defined as any of the following:

Serum total cholesterol ≥ 200 mg/dL.

Serum LDL cholesterol ≥ 130 mg/dL.

Serum HDL cholesterol < 40 mg/dL in men and <50 mg/dL in women.

Serum triglycerides ≥ 150 mg/dL.

4.7. Physical activity

Physical activity levels were classified into sedentary and non-sedentary. All subjects doing physical activity for at least 30 min a day for a minimum of 5 days a week (household activities involving physical effort, walking to and from work involving at least 30 min, manual workers, those performing leisure-time physical activities) were considered non-sedentary. All others were classified as sedentary.

4.8. Socio economic status

We determined the socioeconomic status of the participants using the validated Standard of Living Index tool developed by National Family Health Survey (NHFS) team (IIPS 2000). It consists of 27 items, including consumer durables, agricultural machinery, housing conditions and access to basic services (water, light, fuel, etc). Separate weights are given to each component of the questionnaire based upon prior knowledge of the NHFS regarding the relative significance of these items. The index is calculated by adding up the weights. Possible scores range from 0 to 67. We divided our entire cohort into tertiles based upon the index score. Participants in the upper tertile were classified as high socioeconomic group, those in the middle tertile as intermediate socioeconomic group and lower tertile as low socioeconomic group.

4.9. CAD risk score

All participants had their CAD risk score calculated on the basis of the Framingham Risk Score[28] and will be classified as high risk, intermediate risk and low risk depending on the risk score.

5. Statistical analysis

Data entry was done using CS Pro software version 4.0. The correctness of entries was checked and mistakes and omissions rectified. Statistical processing and analysis were performed using SPSS version 11.0. All proportions were age standardized using WHO population data. Descriptive statistics were conducted by frequency tables and calculation of the point prevalence rates of CAD. The chi-square test and Fisher exact test were used for associations between the dependent variable CAD, and the categorical variables. Crude odds ratios with 95 percent confidence intervals were computed for the variables of characteristics using simple logistic regression. All variables having a p-value less than 0.25 at univariate level were considered eligible for multivariate analysis. Multiple logistic regression was used to find the independent risk factors of CAD. The adjusted odds ratios are presented with 95% confidence intervals. A p-value of <0.05 was considered significant.

6. Discussion

There is paucity of robust and comprehensive contemporary data on prevalence of CAD and its risk factors in India. The importance of this study lies in the fact it provides data on a wide spectrum of parameters from rural and urban parts from across the state. The study is hoped to serve as a baseline data for comparison with similar studies from other parts of the country and also assessing for future trends in the prevalence of the disease.

A limitation of the methodology was that we were not able to randomly select rural areas from across the state for logistic reasons. This has resulted in selecting areas nearer to the coastal regions of the state thus omitting the eastern hilly areas of rural Kerala altogether. However, the cities selected for urban population ensured an equitable geographic distribution across the whole length of the state. Since the rural population was drawn from areas randomized from the adjoining panchayats of the cities, a similar spread in the collected data can be expected.

Conflicts of interest

All authors have none to declare.

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