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## Original Article

# Incidence of cardiovascular diseases and associated risk factors among subjects with type 2 diabetes – An 11-year follow up study



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## ARTICLE INFO

## Article history:

Received 26 January 2013

Accepted 4 December 2013

Available online 19 December 2013

## Keywords:

Cardiovascular disease

Type 2 diabetes

Smoking

Alcohol consumption

India

## ABSTRACT

**Aims:** This study was planned to assess the development of cardiovascular disease (CVD) events over an 11-year period and to identify the associated risk factors that could predict the onset of CVD among subjects with type 2 diabetes.

**Methods:** Retrospective data of 249 patients (M:F 149:100) with type 2 diabetes, from a cohort of 7800 patients, attending a tertiary care center for diabetes from January 2000 to December 2011 were retrieved and analyzed for this study. Sociodemographic and habitual risk factors, baseline diabetes duration, HbA1c and time of onset of CVD and its risk factors were collected from case records. Person-years method was used to calculate incident rate of CVD. Binary logistic regression analyses were done to identify predictors associated with CVD and its risk factors.

**Results:** Incidence of CVD among subjects with diabetes was 5.6 cases/1000 person-years. Nearly 60% developed hypertension and dyslipidemia or both during the 11-year period. The most common complication was neuropathy (14.4%). Smoking [OR (95%CI)] [9.26 (1.6–54.9)] ( $p = 0.014$ ) and heavy alcohol consumption [8.7 (1.1–69.8)] ( $p = 0.04$ ) were significantly associated with CVD. Higher BMI was significantly associated with hypertension and dyslipidemia [2.4 (1.3–4.3)] ( $p = 0.003$ ).

**Conclusions:** Smoking and heavy alcohol consumption were significantly associated with CVD, and increased BMI was significantly associated with hypertension and dyslipidemia among subjects with type 2 diabetes in this study population. These findings emphasize the need for early identification and modification of risk factors associated with CVD events in patients with diabetes.

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<http://dx.doi.org/10.1016/j.ihj.2013.12.009>

## 1. Introduction

The global burden of diabetes is enormous, with an estimated 366 million people living with diabetes worldwide in 2011.<sup>1</sup> India accounted for nearly one-sixth of global diabetes burden in 2011 with about 62 million people affected by diabetes.<sup>2</sup> Regarding the mortality associated with diabetes, globally there were 4.6 million deaths due to diabetes accounting for 8.2% from all causes of mortality. About 48% of the deaths attributed to diabetes had occurred in the people aged below 60 years. In India, 983,000 deaths were attributed to diabetes in 2011.<sup>1</sup> Cardiovascular disease (CVD) is the major cause of death in diabetes and accounts for one-half of all the deaths due to diabetes.<sup>3</sup> Developing countries like India would bear the greater impact of mortality and morbidity associated with diabetes and CVD, as 70–80% of these deaths are expected to occur in such countries.<sup>4</sup>

A case–control study conducted between subjects with diabetes and those without diabetes in urban South India with a median follow-up period of 6 years compared the mortality rate between the two groups and showed a significant two-fold increase in deaths among subjects with diabetes. The study also reported that mortality rate due to CVD in subjects with diabetes was 52.9%, while it was only 24.2% in the normal counterparts.<sup>5</sup> A retrospective study on the causes of mortality due to diabetes in a tertiary care center from India reported vascular diseases as the foremost cause of death in two age groups i.e. more than and less than 56 years among the hospitalized inpatients.<sup>6</sup> This higher rate of premature deaths in diabetes due to CVD can be attributed to the constellation of recognized risk factors such as elevated blood pressure, increased adiposity and hyperglycemic state.<sup>7</sup>

Numerous studies had reported that the basic changes occurring at the vascular level are mediated through insulin resistance in subjects with diabetes as well as prediabetes.<sup>8</sup> In addition, the role of advanced glycation end products in causing premature atherosclerosis and thereby leading to death has also been reported among Finnish women with diabetes.<sup>9</sup> Insulin resistance has been associated with increased serum levels of inflammatory markers such as C-reactive protein (CRP), interleukin-6 and tumor necrosis factor- $\alpha$ , which also play a major role in the vascular endothelial changes in patients with diabetes. Soinio et al<sup>10</sup> reported that patients with type 2 diabetes with high levels of hs-CRP ( $\geq 3$  mg/l) were more likely to have deaths due to coronary heart disease. Several studies had reported the interlinked pathophysiology behind the increased risk of CVD among patients with type 2 diabetes with inconclusive evidences. Eddy et al<sup>11</sup> had simulated a study based on Archimedes model and reported that 42% of myocardial infarction can be prevented by controlling insulin resistance among young adults.

The above-mentioned studies confirm the strong association of various risk factors, including physiological and inflammatory components, with the development of CVD among patients with diabetes. However, there is a paucity of data on the incidence of non fatal CVD events in subjects with type 2 diabetes in India. Hence, the current study was planned with a primary objective to determine the incidence of non fatal CVD

events in patients with type 2 diabetes attending a tertiary care center over a period of 11 years and also to identify its associated risk factors. The secondary objective was to assess the rate of development of CVD risk factors such as hypertension and dyslipidemia and its associated factors among the same cohorts using a retrospective cohort study design.

## 2. Patients and methods

A retrospective cohort study design was followed to address the research question. There were 7800 patients with type 2 diabetes who visited the outpatient department of a tertiary care center in Chennai, Tamil Nadu, from January to December 2000. Out of the 7800 patients, only 350 patients who had 11 years follow-up details, i.e. till December 2011, were selected for this analysis. Out of 350 patients, 90 subjects who had complications and comorbid conditions associated with diabetes at the baseline and 11 subjects with incomplete data at the baseline were excluded from the analysis. Data of the remaining 249 patients with diabetes, but without any complications and other CVD risk factors (hypertension, dyslipidemia) at baseline and who had undergone annual screening for the presence of complications of diabetes for a period of 11 years were included in this analysis. The details were retrieved from the case records maintained in the medical records department. A schematic representation of the recruitment of subjects is illustrated in Fig. 1. Data from subjects both previously diagnosed with diabetes, and diagnosed in the year of 2000 were included in the study.

Socio-demographic details viz., age, gender, habitual risk factors such as smoking and alcohol consumption, baseline HbA1c, BMI, duration of diabetes and family history of diabetes were collected from their case records. The development of CVD risk factors such as hypertension and dyslipidemia during the 11 years, if any, was noted and their time of onset from the baseline was also recorded. JNC VI and VII criteria was followed for the diagnosis of hypertension and similarly, successive NCEP ATP guidelines were used in diagnosing dyslipidaemia.<sup>12,13</sup> The occurrence of disorders pertaining to CVD such as angina, coronary heart disease, peripheral arterial disease and stroke in the subsequent years from 2000 to 2011 was recorded from their case records with a confirmative diagnosis made by the physicians. The tertiary care center follows ADA criteria for the diagnosis of diabetes and its complications.<sup>14</sup>

The study subjects were categorized into current smokers, ex-smokers and non-smokers based on their details in their case records. Non-smokers were those who have never smoked in their lifetime. Ex-smokers were those who had smoked previously and stopped smoking at least 6 months prior to the baseline. Current smoker was defined as a person who had the habit of smoking regularly. Similarly, alcohol consumers were also grouped into 3 categories viz., abstainers group (never consumed alcohol), consumed alcohol occasionally (taking alcohol in moderate level and the frequency of consumption is also less than once a week), and heavy drinkers (who consumed alcohol for almost all the days in a week and the quantity of consumption exceeds 50 ml in male and 30 ml in female per drink).

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