

Kerala Acute Coronary Syndrome Registry

Project Report

ABSTRACT

The global burden of diseased study estimated that there are 31 million people with coronary artery disease in India. Approximately 1.7 million people die of cardiovascular in India. The population of Kerala is at very high risk of death from cardiovascular disease. Extrapolating the Varkala ICDS Block Data it can be surmised that atleast 38 thousand people die of Heart attack in Kerala every year. One may also conjecture that 1.5 Lakh people develop Heart attack in Kerala every year.

There is preponderance of cardiac risk factors in Kerala. The ICMR / WHO study on non-communicable disease estimates that there are 8.72 million hypertensives and 3.48 millions of diabetic in Kerala. Appropriate management & preventive strategies can prevent 80% of Heart attacks.

The epidemic of coronary artery disease warrants an urgent action in terms of expanding public education, control primordial and primary risk factors. The Cardiological Society of India – Kerala Chapter has decided to begin a major preventive cardiology initiative by setting up of a Acute Coronary Syndrome Registry.

The primary objective of this registry is to know the pattern of presentation, risk factor profile, practice pattern of management & to estimate 30 day event rate.

This will be a prospective observational registry designed to enroll patient with ACS in a manner and to collect data representative of entire Kerala population. The study period will be from May 2007 to May 2008. This will involve 100 Cardiologist and 200 Physician Investigators from all over Kerala The data will be collected by the Zonal Coordinators (5 Zones) with the help of field personals.

1. Definition of terms

Acute Coronary syndrome (ACS) refers to a constellation of clinical signs and symptoms produced by acute myocardial ischemia. It comprises unstable angina (UA) and acute myocardial infarction (AMI) associated with ST-segment elevation or depression. The majority of patients with ST-segment elevation ultimately develop a Q-wave AMI (QMI), whereas a minority develops a non Q-wave AMI (NQMI). Patients with angina and no ST-segment elevation have either UA or non ST-segment elevation myocardial infarction (NSTEMI). The two conditions can be differentiated by the presence or absence of the circulating markers of myocyte necrosis. Most patients with NSTEMI do not evolve a Q wave on the 12 lead electrocardiogram (ECG) and are subsequently referred to as having sustained a NQMI; only a minority of NSTEMI patients develop a Q wave and are later diagnosed as having QMI. The spectrum of clinical conditions that range from UA to NQMI and QMI is referred to as ACS.

In the present guidelines, UA and NSTEMI are considered to be closely related conditions whose pathogenesis and clinical presentations are similar but of differing severity; that is, they differ primarily in whether the ischemia is severe enough to cause sufficient myocardial damage to release detectable quantities of a marker of myocardial injury, most commonly troponin I (TnI), troponin T (TnT), or creatinine kinase - MB (CK-MB). Once it has been established that no biochemical marker of myocardial necrosis has been released, the patient with ACS may be considered to have experienced UA, whereas the diagnosis of NSTEMI is established if a marker has been released. In the latter condition, ECG ST-segment or T-wave changes may be persistent, whereas they may or may not occur in patients with UA, and if they do, they are usually transient.

2. Background information and Rationale

Coronary artery disease as assumed epidemic proportion in India. Over 80% of deaths and 85% of disability from cardiovascular disease (CVD) occur in low- and middle-income countries. The Indian subcontinent is home to 20% of the world's population and may be one of the regions with the highest burden of CVD in the world.

The absence of reliable mortality data in the Indian subcontinent has necessitate estimates of the CVD burden based on cross-sectional studies that have been well described previously. In 2003, the prevalence of CHD in India was estimated to be 3-4% in rural areas and 8-10% in urban areas with a total of 29.8 million affected according to population-based cross-sectional surveys. The estimate is comparable to the figure of 31.8 million affected, derived from extrapolations of the Global Burden of Diseases study. However, these numbers are still likely to be underestimates as they do not account for those with silent myocardial infarction or otherwise asymptomatic CHD.

In 1990 there were an estimated 1.17 million deaths from CHD in India, and the number is expected to almost double to 2.03 million by 2010. In addition to the high rate of CHD mortality in the Indian subcontinent, CHD manifests almost 10 years earlier on average in this region compared with the rest of the world resulting in a substantial number of CHD deaths occurring in the working age group.

In Western countries where CVD is considered a disease of the aged 23% of CVD deaths occur below the age of 70 years; this compares with 52% of CVD deaths occurring among people under 70 years of age in India. As a result, the Indian subcontinent suffers from a tremendous loss of productive working years due to CVD deaths: an estimated 9.2 million productive years of life were lost in India in 2000, with an expected increase to 17.9 million years in 2030. The health and economic implications of this staggering rise in early CVD deaths in India are profound and warrant prompt attention from governing bodies and policy makers. The huge burden of CVD in the Indian subcontinent is the consequence of the large population and the high prevalence of CVD risk factors

Urbanization is characterized by a marked increase in the intake of energy-dense foods, a decrease in physical activity, and a heightened level of psychosocial stress, all of which promote the development of dysglycemia, hypertension, and dyslipidemia.

The Indian subcontinent has a higher prevalence of diabetes mellitus than any other region in the world, and 2-3 times the reported prevalence in Western countries. In India alone, an estimated 19.3 million people had diabetes in 1995, and this is expected to almost triple

to 57.2 million in 2025. The Indian Council of Medical Research estimates that the prevalence of diabetes is 3.8% in rural areas, compared with 11.8% in urban areas.

Hypertension is even more prevalent (20-40 % among urban and 12-17% among rural adults, affecting an estimated 118 million inhabitants in India in 2000.

In 2002, a national survey of tobacco use reported that the Indian subcontinent, second only to China in both the production and consumption of tobacco products, had an alarming rate of current tobacco use of 56% among Indian men age 12-60 years. New wave of smoking among India's youth is a serious challenge for future public health.

The Indian Council of Medical Research (ICMR) surveillance project reported a prevalence of dyslipidemia (defined as a ratio of total to HDL cholesterol \geq 45) of 37.5% among adults aged 15-64 years, with an even higher prevalence of dyslipidemia (62%) among young male industrial workers.

Kerala Scenario

The last 30 years has seen a remarkable transition in Kerala. The state is supposed to be in the Stage III of the epidemiologic transition. Cardiovascular death is 50% of the total death and by 2020 it is predicted to go up to 2/3 of the total death. Kerala has the highest life expectancy, the lowest infant mortality rate, and maternal mortality rate. This social transition also has unfortunately led to the highest prevalence of Coronary Artery Disease among all Indian states with a rural prevalence of 7.5% and urban prevalence of 12%. This is more than the so-called North Indian - South Indian divide in prevalence. Even the urban, rural divide seen all over India is not so manifest in Kerala. It is said that Kerala has no villages. In a single medical college hospital in Kerala there has been a more than 20-fold increase in admissions for acute MI from 1966 to 1988. Number of acute MI cases was 220 / 22387 in 1967, which increased to 440/23410 in 1970, 1500 / 33134 in 1975, 4901/43937 in 1982 and 5284 / 43897 in 1987.

The epidemic of Coronary Artery disease in Kerala warrants an urgent actions in terms of expanding public education, control of primordial & primary risk factors by a combination of population based and high-risk interventions & other effective preventive strategies.

It is clear that the population of Kerala is at very high risk of death from cardiovascular disease. Extrapolating the Varkala ICDS Block data it can be surmised that at least 38,000 people die of heart attack in Kerala every year. Otherwise everyday about 110 people die of heart attack somewhere in Kerala. One may also conjuncture that 1.5 lakhs people develop heart attacks in Kerala every year.

This is not surprising when one understands the **preponderance** of risk factor of cardiovascular disease in Kerala. The ICMR / WHO study on Non communicative disease risk factors estimate there are 8.72 million hypertensives in Kerala. The estimated number of diabetic are an astounding figure of 3.48 million. 52.1% of males and 61.4% of female populations has a total cholesterol of > 200 mg/dl.

80% of the heart attacks can be prevented by appropriate management and prevention strategies. Overall there is no programme for the Control of chronic disease in India or

Kerala, possibly because of the greater focus of the health systems on infectious disease and maternal & child health.

Cardiological Society of India Kerala chapter has decided to begin a major preventive Cardiology initiative, which is aimed at not only primary prevention but also reducing the coronary risk factors in the populations. Setting up of Acute Coronary Syndrome registry by the CSI Kerala Chapter is one such initiative. Registries and surveys can collect data rapidly and efficiently, allowing an analysis of a disease condition over particular chronological interval. Registry and survey data allow clinicians to compare the own practice with that of larger national or international reference populations. This provides an important stimulating for improvements in quality and consistency of practice. Registries can provide morbidity and mortality analysis, risk prediction, and resource utilization calculations for particular disease entities.

Primary Objectives:

1. To know the pattern of presentation of Coronary Artery Disease in Kerala.
2. To Asses the risk factor profile.
3. To understand the practice pattern of management.
4. To estimate the 30 day event rate (Death / Revascularization).

Methodology:

This is a Prospective observational registry designed to enroll patients with ACS in an unbiased manner and to collect data representative of entire Kerala population.

The study setting will be secondary and tertiary care hospitals, which manages Acute Coronary Syndrome. Any hospital with Intensive Coronary Care Unit with a Physician / Cardiologist managing Acute Coronary Syndrome are eligible centers.

The Study Period will be for One Year (April 2007 - May 2008).

The Approximate Number of Patients anticipated in the study is 10,000.

This involve 100 Cardiologist and 200 Physician Investigators from all parts of Kerala.

All consecutive patients presented to the hospital in the defined period of time with suspected symptoms of ACS will participate in the Study (Ref: inclusion criteria)

Inclusion Criteria:

- The following patients may qualify for inclusion in the study.
- Men
- Women who are not of child bearing
- AGE 18 years and above

ACS diagnosed by, Chest pain consistent with ACS with at least one of the following:

- ECG changes
- Enzyme elevation
- Documented CAD (Prior MI or proven by CAG)

The patient recruitment:

- All patients >18 years of age.

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