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Review Article

## A Kerala model for cardiovascular research?

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ABSTRACT

India's contribution to cardiovascular research has been dismal with a share of only 1% of total number of papers published in the world during the period 1999–2008. Based on two recent studies published from Kerala, the Kerala ACS Registry and the CSI Kerala CRP Study and four other studies being undertaken in Kerala, we think that a Kerala model for cardiovascular research can be conceptualized. This model which consists of funding by professional organization of cardiologists with wide participation of cardiologists, physicians, health workers, nurses, and in some situations general public, logistics looked after by a central coordinator and study design by panel of experts or institutions of repute in the region and carried out at low cost can be considered for implementation in rest of India. Studies based on such a model may change practice pattern of cardiovascular diseases in India.

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The Kerala model of economic development has been discussed and debated by developmental economists for years. Briefly, Kerala model implies a set of high material quality of life indicators coinciding with low per capita incomes both distributed across Kerala.<sup>1</sup> The idea can be simplified as a model of achievement of high quality output in a resource poor environment. A similar model can be conceptualized in improving cardiovascular research output in India.

India's contribution to medical research has been poor. In an analysis of world medical research output during the period 1999–2008, India's contribution was only 1.59% when compared to 26.19% by US, 8.56% by UK and 3.38% by China. When China improved its medical research output from 0.98% in 1999 to 5.28% in 2008, India improved only marginally from 1.17% in 1999 to 1.88% in 2008. In the same period, 6801 papers published in India on cardiovascular diseases formed only 1.17% of the world's contribution.<sup>2</sup> Clearly, we have to go a long way forward. There are many reasons for this dismal show in medical research in India, foremost among these being inadequate infrastructure, poor accessibility to research funds, weak administrative support, lack of formal training in research methodology, deficient expression

capabilities, unenthusiastic attitude of doctors, and low self-esteem.<sup>3</sup>

Recently, two important studies on Cardiovascular Sciences were published from Kerala, the Kerala Acute Coronary Syndrome (ACS) Registry and the Cardiological Society of India (CSI), Kerala Chapter Coronary Artery Disease and its Risk Factors Prevalence Study (CSI Kerala CRP Study). These studies had many aspects which may be adopted for future research.

### 1. The Kerala ACS Registry

It is the largest acute coronary syndrome (ACS) registry ever conducted in India. It enrolled prospectively 25,748 patients with ACS from 125 hospitals spread across Kerala during the period 2007–2009.<sup>4</sup> Mean age of the patients was 60.4 years (men 77.4%). ST-segment myocardial infarction (STEMI) accounted for 37%, non-STEMI 31%, and unstable angina 32% of ACS patients. Thrombolytics were used in 41% of STEMI, 19% of non-STEMI, and 11% of unstable angina admissions. Symptom onset to presentation of more than 6 h was noted in 41% of STEMI patients. In-hospital medical therapy was relatively high overall for all groups, with anti-platelet therapy being the most common (97%). Discharge medication rates were variable and generally suboptimal (80%). Angiography and Percutaneous Coronary Intervention (PCI) use was substantially lower when compared to other registries from the developed world.<sup>4</sup> Rate of thrombolysis in STEMI was lower than in another large Indian ACS registry, the CREATE Registry.<sup>5</sup>

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Less than 50% of STEMI patients received reperfusion in the form of thrombolysis/PCI or CABG. The registry opened a window of opportunities for ACS care in Kerala like improving symptom onset to door time in STEMI, improving reperfusion in STEMI using thrombolysis or angioplasty, improving discharge medication prescription in ACS, avoiding inappropriate thrombolysis, and improving in-hospital mortality.

## 2. CSI Kerala CRP Study

This was a community-based cross-sectional study in Kerala, where 5167 adults (mean age 51 years, men 40.1%) were selected using a multistage cluster sampling method.<sup>6</sup> Information on socio-demographics, smoking, alcohol use, physical activity, dietary habits and personal history of hypertension, diabetes, and coronary artery disease (CAD) was collected using a structured interview schedule. Anthropometry, blood pressure, electrocardiogram, and biochemical investigations were done using standard protocols. Results showed that age-adjusted prevalence of definite CAD was 3.5%, while prevalence of any CAD was 12.5%. There was no difference in definite CAD between urban and rural populations. Most risk factors for CAD were highly prevalent in the state. Hypertension was detected in 28%, diabetes in 15%, high total cholesterol in 52%, and current smoking among men in 28%. Authors of the study concluded that prevalence of definite CAD in Kerala increased nearly three times since 1993 without any difference in urban and rural areas. They suggested both population and individual level approaches to address the high levels of CAD risk factors to reduce the increasing prevalence of CAD in this population.

## 3. What was common in the two studies?

Both studies were funded by the Kerala chapter of Cardiological Society of India, a professional organization of cardiologists of Kerala. Apart from saving the hurdle of getting financial support, this ensured backing of the whole cardiology community of the state for the study. The design and methodology of the studies were discussed in detail at the meetings of Kerala chapter and progress was presented periodically. In the case of Kerala ACS Registry, the cardiologists and physicians who participated in the study had great sense of involvement. They cooperated voluntarily and encouraged their paramedical team to provide the necessary support for recruiting patients, getting informed consent, helping to record the case report forms (CRF), and ensuring entry of follow-up data. In the CSI Kerala CRP Study, credibility of CSI- Kerala Chapter helped in getting the active participation of local people, which was crucial for the success of the study. At each recruitment center, several meetings were held under the supervision of local administrative bodies, with participation of elected ward/division representatives, doctors from the local government hospitals, health centers and private clinics, health workers, and the public. In these meetings, doubts raised were clarified, and the purpose of study was explained. Being a study carried out by Cardiological Society of India- Kerala Chapter helped immensely to get the trust of the people.

Central role played by the coordinators for these studies needs to be emphasized.

Two of the authors were the coordinators for Kerala ACS Registry and CSI Kerala CRP Study (MP and GZ respectively). Having a central coordinator solved to a large extent the problem of inadequate research infrastructure in our country. They were responsible for submitting the initial proposal. Once the projects were approved, they finalized the design and methodology, selected the co-investigators, developed communication channels, set up the steering committee, and obtained approval of ethics

committee. They also looked after purchase of equipments and maintenance of proper book of accounts.

Lack of prior research experience is often mentioned as a stumbling block in our country. In Kerala ACS Registry, a panel of experts constituted by heads of academic institutions in Kerala prepared the protocols and CRFs. The design and methodology of CSI Kerala CRP Study was developed by public health department of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum.<sup>7</sup> This considerably reduced the burden on the investigators.

However, more important was the participation of large number of people in these studies, often without any monetary gain. In the case of Kerala ACS Registry, cardiologists and physicians in 125 hospitals voluntarily participated in the project and attended the meetings. In addition, the contribution of the nurses in ICUs was invaluable. They attended the sessions held periodically for imparting knowledge on ACS management and training the proper method of filling the CRFs, without receiving any remuneration. Their enthusiasm for learning and being part of the project was a revelation for the investigators. In the case of CSI Kerala CRP Study, the tireless work of the 'Kudumbashree' (a female-oriented, community-based, poverty reduction project of the government of Kerala) workers and ASHAs (accredited social health activists), mostly women, need to be appreciated. Each of them was asked to visit all households in their allotted area three times, firstly to list the members of each household, secondly to invite the selected participants from each household to the designated center for data collection, and thirdly to hand over the results of investigations and brief recommendations. They were paid only very small amount, yet were very active and primarily responsible for the good response rate of the study. In both studies, special care was taken to impart knowledge on research methodology to the investigators. In the Kerala ACS Registry, investigators were invited periodically to learn about registries in general and registries on ACS. In CSI Kerala CRP Study, two workshops were done at SCTIMST public health department, one on methodologies of epidemiologic studies and another on biostatistics.

These were low budget studies. The budget for Kerala ACS Registry was Rupees two million (Rupees 500,000 from national CSI) and that of the CSI Kerala CRP Study was Rupees 2.5 million. It is worthwhile to note that the concept of low budget collaborative research studies on cardiovascular disease is not new and has been utilized in at least three previous studies from India, namely early phase of INTERHEART study,<sup>8</sup> CREATE registry,<sup>5</sup> and India Heart Watch study.<sup>9</sup> Kerala studies differed in that they were supported by the Kerala chapter of CSI, which helped in getting the cooperation of not only cardiologists and physicians of the state but also the public.

## 4. What constitutes the Kerala model of cardiovascular research?

We, therefore, propose that even in a resource-poor setting, high quality cardiovascular research can be undertaken successfully. Such a model envisages funding of the study by a professional organization like Kerala Chapter of Cardiological Society of India to ensure the whole-hearted support and involvement of all cardiologists. There is a need to identify a central coordinator who can remedy deficiencies of research infrastructure. Such a model may involve not only the cardiologists and physicians, but also health care workers and nurses if it is a hospital-based study and the health care workers, members of local self Government, and general public in studies where screening of asymptomatic people is involved. The Kerala model implies low budgetary allocation and studies may be carried out by people's participation.

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