ISSN: 0975-833X

*Available online at http://www.journalcra.com*

*International Journal of Current Research*
*Vol. 11, Issue, 01, pp.80-82, January, 2019*

**DOI: https://doi.org/10.24941/ijcr.33590.01.2019**

**INTERNATIONAL JOURNAL OF CURRENT RESEARCH**

## RESEARCH ARTICLE

# TRIAL DESIGN AND RATIONALE: PREMATURE CORONARY ARTERY DISEASE (PCAD) REGISTRY PROSPECTIVE MULTI-SITE 5YEAR INTEGRATED CARDIOLOGY CLINIC OF PREMATURE CAD(< 40YRS) IN SOUTH INDIAN POPULATION. (CTRI/2018/03/012544)

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**ARTICLE INFO**

*Article History:*
Received 22nd October, 2018
Received in revised form
04th November, 2018
Accepted 02nd December, 2018
Published online 30th January, 2019

*Key Words:*

Premature Coronary Artery Disease,
Integrated Cardiology Clinic,
Prospective observational study.

**ABSTRACT**

AIMS To study the uniqueness of Premature coronary artery disease in Indians with respect to clinical behaviour, risk factor profile, and treatment response. METHODS Registered under Clinical Trials Registry of India (CTRI/2018/03/012544). This is a Prospective Multisite Descriptive Observational study of young Indians (≤ 40yrs) with CAD from index admission till 5yrs follow-up. The clinical presentation, line of management, angiographic profile, Hospital course, and clinical follow up for next 5yrs will be documented All patients will be provided Integrated cardiology care starting at hospital admission and continued during follow up. CONCLUSION Findings may be used to form risk-prediction models for young Indians and provide longitudinal clinical follow-up data of long-term outcomes of different treatment strategies



***Citation: Rahul S. Patil, Laxmi H. Shetty, Satvic C. M., Vijaykumar J. R., Raghu T.R., Manjunath C.N. et al.*** **2019.** "TRIAL DESIGN AND RATIONALE: Premature Coronary Artery Disease (PCAD) Registry Prospective Multi-site 5year INTEGRATED CARDIOLOGY CLINIC of Premature CAD(< 40yrs) in South Indian Population. (CTRI/2018/03/012544)", *International Journal of Current Research*, 11, (01), 80-82.

## INTRODUCTION

Cardiovascular disease is the leading cause (28%) of death in India (Enas and Salim Yusuf, 1999). The annual CVD mortality in India was predicted to rise to 4.77million (Rajeev Gupta *et al.,* 2012) making India the Cardiovascular disease capital of the world by 2020. The risk of Coronary Artery Disease in Asian Indians is four times that of Caucasians, six times of Chinese and 20 times of Japanese populations (Enas *et al.,* 1996). Indians are prone to CAD at a much younger age (Janus *et al.,* 1996). Approximately 50% of first heart attacks occurs before 55 years and 25% occurs before 40 years age (Enas, 2011). The Disability Adjusted Life Years (DALY) for Premature Coronary Artery Disease (PCAD) in Indians is highest among any other region in the world (Yusuf *et al.,* 2004). This indicates not just lack of primary prevention programmes but also ineffectiveness of secondary prevention. Landmark CAD studies have mostly engaged Caucasians, generating western guidelines which have failed in disease prevention in Indians (Dawber *et al.,* 1959). This is due to fundamental differences in pathophysiology of Indian PCAD, making it a distinct entity compared to Caucasians.

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Hence there is a need for long term large scale studies to ascertain clinical behavioural dynamics of Indian PCAD.

## METHODS

The PCAD registry is registered under Clinical Trials Registry of India (CTRI/2018/03/012544) and is a prospective multisite descriptive observational study examining young Indian adults aged forty years or below with CAD from the point of index admission and follow-up till a period of 5 years (Figure 1). Site of study is Sri. Jayadeva Institute of Cardiovascular Sciences and Research is the largest dedicated Cardiac centre in South East Asia with a total Bed capacity of 1150 with its Headquarters in Bangalore and two branches in Mysuru and Kalburgi. It is an Autonomous institute under Government of Karnataka. Inclusion criteria for this study were (1) Age ≤40 years, (2) All patients with index admission for Ischemic Heart disease, as proven by either (i) Documented episode of Acute Coronary Syndrome or (ii) Chronic Stable angina with documented evidence of Coronary artery disease. Exclusion criteria were (1) Myocarditis / Cardiomyopathies / Pulmonary embolism (2) Previously diagnosed case of CAD or on medications like antiplatelets, statins.

On admission to hospital, details of presentation such as onset, duration and nature of pain, associated symptoms, time gap, vitals. door-to-balloon and door-to-Needle time will be documented. Based on the cardiovascular risk factor profile of the patients, they will divided into risk factor categories (Table 1.) Depending on diagnosis, patient preference, availability of social health insurance schemes, patients will be offered treatment in line with current ACC/AHA guidelines for management of ACS. All modalities such as thrombolysis, Primary Percutaneous Coronary Intervention (PCI), facilitated PCI, Anticoagulation followed by diagnostic elective coronary angiography will be available depending on presentation. Based on the line of treatment given, the patients will be grouped into treatment categories (Table 2.) and will be followed up accordingly. From the point of admission, till discharge every single clinical event, tests, procedures, complications will be recorded. As a part of Integrated Cardiology Clinic (Figure 2) approach to these patients, they will be provided free

a) Yoga introduction and training
b) Di*et a*nd nutrition counselling
c) Smoking de-addiction
d) Diabetic treatment
e) Lifestyle counselling

**Table 1. Treatment categories**

| TREATMENT CATEGORIES | | | |
|---|---|---|---|
| STEMI | | EVOLVED MI NON - STEMI UNSTABLE ANGINA | CHRONIC STABLE ANGINA TMT +VE |
| PRIMARY PCI | THROMBOLYSIS | ANTICOAGULATION | |
| I | II | III | IV |
| OPTIMAL MEDICAL THERAPY | INVASIVE / MEDICAL THERAPY | | |
| | CORONARY ANGIOGRAM A | | OPTIMAL MEDICAL TREATMENT B |
| | PCI $A_1$ | CABG $A_2$ | OMT $A_3$ |
| | $IIA_1$ | $IIA_2$ | $IIA_3$ | II B |
| | $IIIA_1$ | $IIIA_2$ | $IIIA_3$ | III B |
| | $IVA_1$ | $IVA_2$ | $IVA_3$ | IV B |

**Table 2. Risk factor categories**

| RISK FACTOR CATEGORIES | | |
|---|---|---|
| FAMILY HISTORY NEGATIVE | CONVENTIONAL RISK FACTOR | FAMILY HISTORY POSITIVE |
| I B | SMOKING | I A |
| II B | DIABETES | II A |
| III B | HYPERTENSION | III A |
| IV B | DYSLIPIDEMIA | IV A |
| V B | NO TRADITIONAL RISK FACTORS | V A |

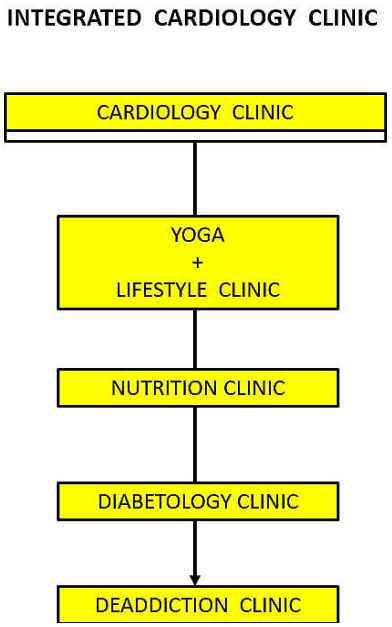


**Figure1. Structure of Integrated Cardiology Clinic**

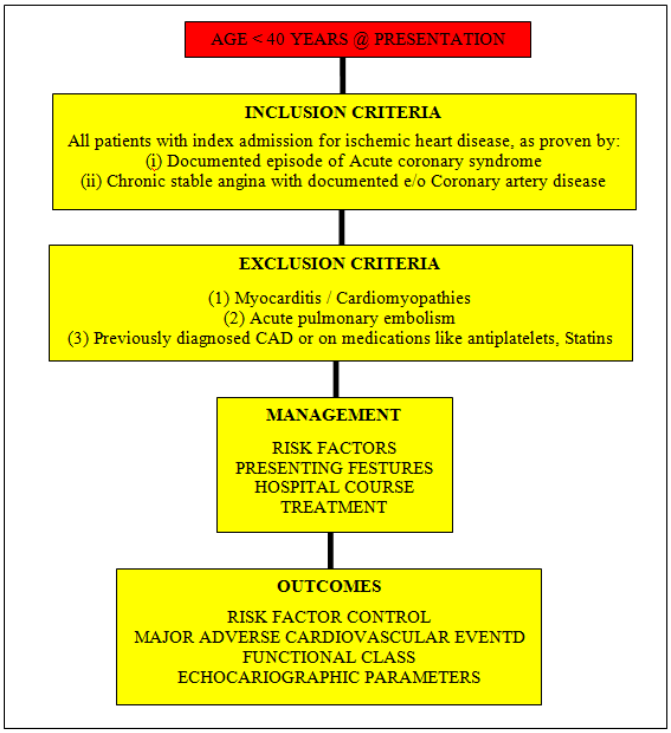


**Figure 2. Methodology**

The standard schedule of follow-up visits for every patient is at 3 months followed by bi yearly / yearly visits wherein following parameters like Physical parameters, Drug compliance, Diet, Present Health status, interim CV events, Biochemical parameters (Sugars, cholesterol), Echocardiographic parameters At every follow-up visit, patients will be provided facilitated Integrated Cardiology consultation. During these sessions, firstly patient compliance with previous instructions will be documented. Further, additional instructions in accordance with the phase of cardiac rehabilitation of the patient will be provided. For statistical analysis, the Clinical characteristics will be compared across different subgroups, including sex, race, socioeconomic status. Continuous variables will be summarized by means/SDs and compared with t tests or Wilcoxon test. Categorical variables will be tabulated by frequencies and proportions across groups

and compared with $\chi 2$ or Fisher exact tests. Regression modelling will be performed to adjust for differences and confounding and examine relationships between different subgroups. Cox proportionalhazards modelling will be performed for time-to-event analyses.

## DISCUSSION

The PCAD Registry is designed to register an estimated total of 10,000 patients in 3 participating centre's between April 2017 to 2022 making it the largest Registry for PCAD till date. PCAD registry is a component of the larger Project PCAD which is a first-of-its-kind combined Registry, Clinic, Research centre for PCAD in Indians. This project has multiple subdivisions for diabetology, nutrition, genetics and will investigate various unique aspects of Indian PCAD like advanced lipid profile, metabolic and hormonal (testosterone, insulin, vit D) profile under grants from the government. PCAD constitutes a specific subset of population having different clinical profile and prognosis as compared to older patients. Especially in Asian Indians, the metabolic profile is very unique compared to other ethnic population in numerous ways making them more prone to PCAD. Asian Dyslipidaemia, Hyper Lipoprotein(a), hyperhomocysteinemia, increased prevalence of metabolic syndrome at a lower BMI and shorter waist circumference make Young Indians to have 2 fold risk of CAD for any combination of risk factors compared to Caucasians To reduce this high risk of CAD in Asian Indians, the treatment has to be more aggressive and should begin at a lower threshold than is recommended for western populations. Results from this registry may be used to form future risk-prediction models designed specifically for young Indians. Increased thrombotic milieu underlying PCAD is distinct from underlying calcific and atherosclerotic milieu in elderly population. Hence management strategies in these two groups could be different. The occurrence of spontaneous thrombosis without atherosclerosis is particularly described in young patients (Otto *et al.,* 2014). Primary PCI in STEMI with high thrombus is associated with a higher incidence of adverse cardiac events (Rezkalla *et al.,* 2008) due to distal embolization causing impaired myocardial perfusion. Therefore, several pharmacological and interventional strategies, such as intracoronary thrombolysis, thrombectomy, GpIIb/IIIa inhibitors aiming at reducing thrombus burden, have been developed in order to improve prognosis. The PCAD registry will provide longitudinal clinical data which will enable follow-up of long-term outcomes of different strategies.

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