



Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj



Original Article

The design and rationale of the primary angioplasty registry of Kerala

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ARTICLE INFO

Article history:

Received 24 December 2016

Accepted 28 May 2017

Available online xxx

Keywords:

Acute myocardial infarction

Primary angioplasty

Prospective registry

ABSTRACT

Background: ST-elevation myocardial infarction (STEMI) continues to be a major cause of cardiovascular mortality in Kerala, India. Timely primary percutaneous coronary intervention (PCI) is the recommended reperfusion strategy for STEMI. There is limited data on the safety, effectiveness, equity and efficiency of regional primary PCI services in India.

Methods/Design: The primary angioplasty registry of Kerala is a clinician-initiated prospective state-wide longitudinal hospital-based registry of patients undergoing primary PCI for STEMI. The registry aims to document the efficacy and safety of the real world use of primary PCI in Indian patients presenting with STEMI, in order to achieve regional adoption of global standard performance indicators. In addition, the registry would analyze procedural variations in the performance of primary PCI and assess its impact on relevant patient centered outcomes. We plan to enroll 6000 STEMI patients, undergoing primary PCI, across 48 hospitals. These patients would be followed up for a minimum of 1 year.

Conclusions: The primary angioplasty registry of Kerala would help analyze the quality and outcomes of primary PCI services in Kerala, thereby yielding insights that can help limit unacceptable procedural variations in the performance of primary PCI. Identifying deviations from guideline based therapies can form the basis of quality improvement programs, which in turn will enable hospitals to achieve better patient outcomes.

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1. Background

Cardiovascular disease is the leading cause of mortality in India, and more so in the Southern Indian state of Kerala.^{1,2} The burden of cardiovascular deaths in this state now exceeds that of some industrialized nations.² Kerala has a high prevalence of conventional cardiovascular risk factors including diabetes, hypertension, dyslipidemia and central obesity.³ When seen in the context of a projected increase in the prevalence of diabetes over the next few decades,⁴ an alarming increase in the incidence of cardiovascular diseases can be expected.

Acute coronary syndromes, especially ST-segment elevation myocardial infarction (STEMI), continues to be the major cause of cardiovascular mortality in Kerala.⁵ At 8.2%, STEMI mortality rate in Kerala is high, considering the fact that the mean age of the affected population is only 60.4 years.⁵ In order to reduce mortality and improve long-term outcomes in patients presenting with STEMI, it is essential to develop systems of care to facilitate rapid reperfusion using appropriate pharmacological and/or interventional therapies.⁶ Timely primary percutaneous coronary intervention (PCI) performed by experienced operators is the recommended reperfusion strategy for STEMI.⁶ One observational study from Kerala has shown substantially higher in-hospital mortality rates among STEMI patients undergoing thrombolysis as compared to those undergoing primary PCI (11.2% versus 5.2%).⁷ This may be due to inequitable use of primary PCI, including the effect of gender bias.⁷ Over the past five years, Kerala has witnessed a rapid expansion in the number of PCI-capable hospitals which can be designated as receiving centers for STEMI

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<http://dx.doi.org/10.1016/j.ihj.2017.05.025>

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patients. With 97 cardiac catheterization laboratories in the state of Kerala as on 1st April 2015, at the start of the study, there was 1

cardiac catheterization laboratory available per 344,400 population, thereby substantially increasing the number of patients who

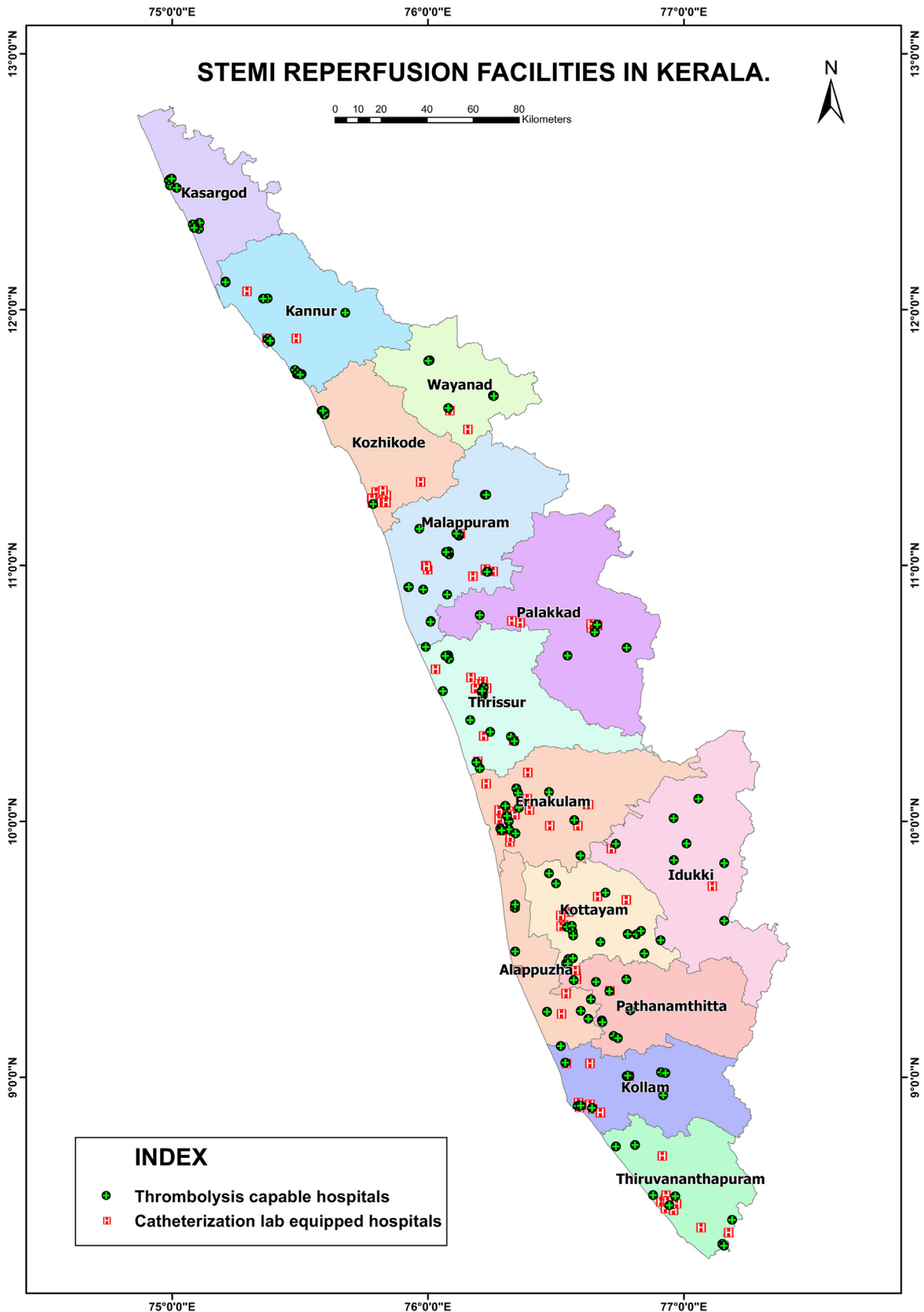


Fig. 1. ST-segment elevation myocardial infarction reperfusion facilities in Kerala, India, as on July 2016.

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