



## Original Article

## The design and rationale of the primary angioplasty registry of Kerala



Jabir A<sup>a,\*</sup>, Anoop Mathew<sup>b</sup>, Sunitha Viswanathan<sup>c</sup>, Ashraf S M<sup>d</sup>, Placid Sebastian<sup>d</sup>,  
Prasannakumar C K<sup>e</sup>, George Koshy A<sup>c</sup>, Sunil Pisharody<sup>f</sup>, Rony Mathew<sup>a</sup>, L. Jeyasheelan<sup>g</sup>

<sup>a</sup> Lise Hospital, Kochi, Kerala, India

<sup>b</sup> MOSC Medical College, Kolencherry, Kerala, India

<sup>c</sup> Government Medical College, Thiruvananthapuram, Kerala, India

<sup>d</sup> Sahakarana Medical College, Pariyaram, Kannur, Kerala, India

<sup>e</sup> Jubilee Mission Medical College, Thrissur, Kerala, India

<sup>f</sup> E M S Co-operative Hospital, Perinthalmanna, Kerala, India

<sup>g</sup> Christian Medical College, Vellore, Tamilnadu, India

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## 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.<sup>1,2</sup> The burden of cardiovascular deaths in this state now exceeds that of some industrialized nations.<sup>2</sup> Kerala has a high prevalence of conventional cardiovascular risk factors including diabetes, hypertension, dyslipidemia and central obesity.<sup>3</sup> When seen in the context of a projected increase in the prevalence of diabetes over the next few decades,<sup>4</sup> 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.<sup>5</sup> 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.<sup>5</sup> 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.<sup>6</sup> Timely primary percutaneous coronary intervention (PCI) performed by experienced operators is the recommended reperfusion strategy for STEMI.<sup>6</sup> 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%).<sup>7</sup> This may be due to inequitable use of primary PCI, including the effect of gender bias.<sup>7</sup> 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

\* Corresponding author.

E-mail addresses: [drjabir@yahoo.co.in](mailto:drjabir@yahoo.co.in) (J. A.), [anoopmatts@gmail.com](mailto:anoopmatts@gmail.com) (A. Mathew), [sunuthaviswan@gmail.com](mailto:sunuthaviswan@gmail.com) (S. Viswanathan), [ashsmfz@yahoo.com](mailto:ashsmfz@yahoo.com) (A. S M), [placidseb@gmail.com](mailto:placidseb@gmail.com) (P. Sebastian), [pkumarck@gmail.com](mailto:pkumarck@gmail.com) (P. C K), [ageorgekoshy@gmail.com](mailto:ageorgekoshy@gmail.com) (G.K. A.), [sunilpisharody@yahoo.co.in](mailto:sunilpisharody@yahoo.co.in) (S. Pisharody), [drronymathew@yahoo.com](mailto:drronymathew@yahoo.com) (R. Mathew), [ljey@hotmail.com](mailto:ljey@hotmail.com) (L. Jeyasheelan).

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

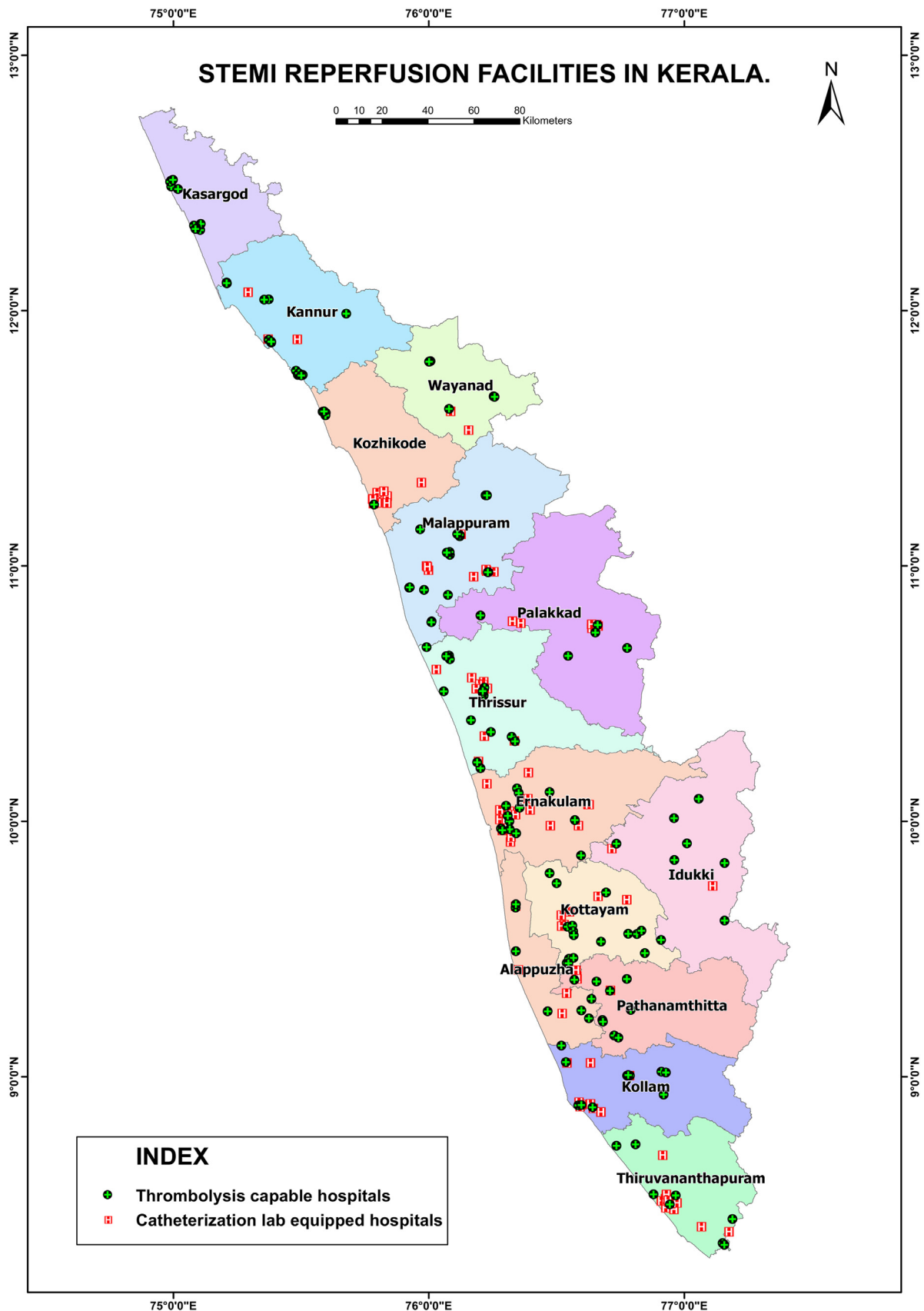


Fig. 1. ST-segment elevation myocardial infarction reperfusion facilities in Kerala, India, as on July 2016.

may have timely access to emergency cardiac catheterization services. As per available Indian data, the rates of PCI for STEMI had shown only a marginal improvement from 8.0% in the CREATE registry (2001,2005)) to 12.9% in the Kerala ACS registry (2007–2009).<sup>5,8</sup> The delivery of primary PCI services in Kerala continue to be fragmented and decentralized with no formal systems of STEMI care. We believe that the rapid expansion of cardiac catheterization services in Kerala affords us a unique opportunity to assess the impact of this healthcare infrastructure improvement on STEMI mortality and outcomes. There is an urgent need to implement a state-wide observational registry to profile patients presenting with STEMI and to analyze the safety, effectiveness, equity and efficiency of primary PCI services. Such a registry would help analyze the quality of STEMI care among the PCI capable state hospitals and identify deviations from guideline-recommended therapies that can be improved upon [Fig. 1](#).

1.1. The primary angioplasty registry of Kerala

The primary angioplasty registry of Kerala (PARK) is a clinician initiated ongoing, prospective state-wide longitudinal hospital based registry of patients undergoing primary PCI for STEMI. The registry started enrolling patients from April 2015. The registry was funded by the Cardiological Society of India-Kerala Chapter.

2. Registry design

2.1. Participating hospitals

At the start of the study, as on 1st April, 2015 there were 219 private and 36 public hospitals providing emergency reperfusion services for patients presenting with STEMI. Of these, 92 hospitals had cardiac catheterization laboratories, including 9 hospitals owned by the government or public co-operative societies. Five out of these 92 catheterization lab-equipped hospitals were not offering primary PCI services. Cardiology departments of the remaining 87 hospitals were invited to take part in the registry. Eighty-one PCI-capable centers responded, out of which 48 hospitals finally participated in the registry. Hospitals performing  $\leq 5$  primary PCIs per year will be excluded from the final analysis.

2.2. Patient inclusion criteria

All patients, more than 18 years of age, presenting with acute STEMI with chest pain/discomfort of  $< 12$  h duration designated to reperfusion therapy with primary angioplasty were included in the study. Diagnostic ST- elevation in the absence of LV hypertrophy or left bundle branch block was defined as new ST- elevation at the J point in at least two contiguous leads of  $> 2$  mm in men or  $> 1.5$  mm in women in leads V2-V3 and/or  $\geq 1$  mm in other contiguous chest leads or limb leads. At least one cardiac biomarker elevation above the 99th percentile upper reference limit was required for confirmation of diagnosis. New onset or presumed new onset left bundle branch block was also considered as STEMI equivalent. Patients with acute STEMI presenting to PCI-capable centers 12–24 h after the onset of symptoms were also included, if the patient had clinical and/or electrocardiographic evidence of ongoing ischemia. A consent waiver was obtained, from the ethics committee, for patients who died or were too ill to give consent.

Screening logs were maintained in the hospital emergency rooms, cardiac catheterization labs and coronary care units. These screening logs were reviewed by study coordinators, for consistency, in order to detect potentially missed cases. Data sheets of patients transferred between two separate STEMI receiving hospitals were merged to form a single entry.

2.3. Patient exclusion criteria

We excluded patients presenting with STEMI  $> 24$  h after symptom onset and those presenting between 12 and 24 h with no clinical and/or electrocardiographic evidence of ongoing ischemia. Patients who were thrombolysed, either at the referring hospital or at the STEMI receiving center, were excluded irrespective of the dose of the lytic therapy. Patients presenting initially with unstable angina or non-ST elevation myocardial infarction and subsequently developing STEMI in-hospital were excluded. In addition, patients hospitalized for non-cardiac causes who subsequently develop in-hospital STEMI were also excluded.

2.4. Data standards and quality assurance

Data elements were captured by pre-designated staff members at specified points in the chain of STEMI care. Every effort was made to capture data in real time or as soon as the patient was transferred out of the pre-specified location.

Site of care	Personnel in charge of data-entry	Data Entry Sections
Emergency room	Admitting physician/ cardiology house staff	Timeline of patient contact (including time of first medical contact and onset-to-door time) Demographics History of cardiac disease Relevant risk factors Revascularization strategy chosen
Catheterization lab	Nursing staff/ cardiology technician Interventional cardiologists	Procedural details and timing (including door-to-balloon time) Quantitative coronary angiogram Lesion characteristics Vascular access details Complications
Coronary care unit	Nursing staff	Relevant blood investigations Medications including timing
Ward	Nursing staff	Discharge medications Discharge status
Any location	Research Nurse/ Cardiologist	Adverse outcomes In-hospital events Cause of death

If the patient was directly shifted to the catheterization laboratory, bypassing the emergency room, the corresponding sections were merged into a single entry. Hospitals were given the option of having either an entirely internet-based standardized electronic case report form (e-CRF) or a paper-based case report form. Moreover, paper-based case report forms could be used in selected locations only (like in wards), where internet access was not available, in order to supplement the web-based case report form.

Prior to patient discharge, the site research nurse or coordinator was intimated and the completeness of the physical case report form was checked. The web-based e-CRF had built in checks including mandatory fields, time-limits from the initial patient contact, pre-specified ranges for value fields and built-in notifications of outcome definitions, in-order to avoid transcriptional errors and ensure validity and completeness of the entered data.

Trained research nurse-data abstracters visited the participating hospitals once a month and reviewed the medical records of the patients and retrieved those data items which were missing in the case report forms but was documented in the patient’s medical records. These medical records were reviewed to determine if any in-hospital adverse outcomes were left undocumented or was misclassified in the case report forms.

## 2.5. Follow up

Follow-up information was prospectively obtained, during the monthly site visits, from the medical records or by a direct telephonic interview with the patients, at pre-defined time intervals of 30 days and 1 year. Telephonic interviews were performed by independent research nurses. Enrolled patients were identified on the medical records and, if possible, on the hospital information system, triggering an intimation to the research coordinator in case of a readmission.

## 2.6. Data linkages

The PARK is linked to the TRUST-Outcomes registry of the CSI-Kerala Chapter. Timeliness of Reperfusion in patients with ST-elevation myocardial infarction and Outcomes (TRUST-Outcomes) registry is the first phase of a multicenter collaborative effort to establish a system of care for STEMI management in Kerala. TRUST-Outcomes will analyze the composition of the total-ischemic-time and assess its impact on patient-centered outcomes. The time of onset of chest pain, the time of first medical contact, door-in door-out time at the referring hospital, transport time and various components of the door-to-balloon time will be documented in this registry. Coding of data points is the same in both the registries. The TRUST-Outcomes registry has data points coded against all the inclusion and exclusion criteria of PARK. All relevant outcomes definitions are also the same. All data points documented in PARK are also captured in TRUST-Outcomes registry. TRUST-Outcomes registry collects data from all consecutive STEMI patients, meeting pre-defined inclusion criteria, across 16 of the 92 PCI-capable hospitals in Kerala.

## 2.7. Objectives of the registry

The main objectives of PARK are: 1. 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 standard performance indicators and benchmarking of interventional procedures. 2. To assess the baseline characteristics, risk profiles, and short as well as long-term outcomes of patients undergoing primary PCI for STEMI. 3. To document procedural variations in the performance of primary PCI and assess its impact on relevant patient centered outcomes, with particular emphasis on the choice of vascular access, trends in the use of thrombus aspiration and routine use of post-dilatation after stent deployment.

Registry Objective	Primary Outcome	Time frame
Document the efficacy and safety of the real world use of primary angioplasty in Indian patients presenting with STEMI.	The primary efficacy outcome is a composite of all-cause mortality, non-fatal recurrent myocardial infarction and repeat revascularization	1 year
Post-dilatation and outcomes	Primary composite outcome of all cause death/recurrent MI and target vessel revascularization	1 year
Radial versus femoral access: impact of vascular access on outcomes	Primary composite outcome of death/recurrent-MI/stroke and non-CABG major bleeding	1 year
Outcomes with and without thrombus aspiration during primary PCI in patients presenting with STEMI	Primary efficacy outcome of death, recurrent MI, cardiogenic shock or hospitalization for heart failure. Net clinical benefit outcome: the binary occurrence of primary efficacy outcome or stroke at 1 year. Main safety outcome: stroke at 30 days.	1 year

Standardized definitions were used for the pre-defined complications and outcomes. The presence and severity of bleeding complications were documented using the Thrombolysis in Myocardial Infarction (TIMI) bleeding classification in all patients [9]. For the subset of patients linked from the TRUST Outcomes registry, bleeding complications were additionally documented using the standardized hierarchical bleeding classification system proposed by the Bleeding Academic Research Consortium [10]. Stent thrombosis was documented and classified according to the Academic Research Consortium definition of stent thrombosis [11]. Hospitals will be classified into low ( $\leq 36$  primary PCIs per year), intermediate (36–60 primary PCIs per year) and high ( $> 60$  primary PCIs per year) volume hospitals according to the annual primary PCI volumes.

## 2.8. Statistical analysis

Data will be entered using a dedicated online portal that will be available at each recruiting hospital. Data will be analyzed using STATA software (Statacorp, College Station, TX). The continuous variables will be screened for outliers using histograms and Box-Cox plots. The categorical variables will be screened using distributions. In addition, the normality of distribution will be assessed using Q-Q plots, and numerical methods including the Shapiro-Wilk test. Continuous variables will be summarized as mean with standard deviation for normally distributed parameters and as median with interquartile ranges for not-normally distributed variables. Categorical variables will be summarized as number counts with percentages.

We plan to enroll 6000 patients undergoing primary angioplasty for STEMI in the state of Kerala. In 2015, there were 8704 primary angioplasties reported to the Interventional Cardiology Council of Kerala. One of the objectives of this study is to identify how variations in the performance of primary PCI, at individual participating hospitals, affect patient outcomes. Participating hospitals will be divided into tertiles depending on the frequency of use of the pre-defined procedural steps during primary PCI, including the use of radial vascular access, use of thrombus aspiration and use of post-dilatation after stent deployment. For calculating the sample size, we expect the proportion of patients developing the composite outcome in the high tertile hospital group to be as good as or non-inferior to the proportion of patients developing the composite outcome in the low tertile hospital group. Assuming the occurrence of the composite outcome in 10% of patients, with a non-inferiority margin of 3%, power of 80% and alpha error of 5%, the required sample size needed in each tertile group is about 1250.

## 3. Discussion

How can registry data help improve STEMI care in order to achieve better patient outcomes?

A large regional dedicated clinical registry would help document the clinical profile of patients presenting with STEMI, variations in therapeutic interventions and patient outcomes. This would in turn help identify deviations from standards of care and assess how these deviations adversely impact outcomes. In order to establish an efficient system of care for rapid reperfusion in STEMI patients, these clinically validated benchmarks and checks should be incorporated into standardized protocols.

Achieving successful and rapid reperfusion in patients presenting with STEMI involves a complex interplay of individual components of the regional systems of care including pre-hospital care, patient transfer protocols, choice of reperfusion strategy, the timing, dose, route and duration of administration of a variety of pharmacological agents, coronary intervention techniques,



bleeding avoidance strategies, hemodynamic support and intensive care. With so many contributing factors, it may be difficult to decipher the impact of a particular therapeutic intervention using observational data alone. Nonetheless, registry data can help us draw conclusions on the safety, timeliness, equity of use and comparative effectiveness of therapeutic interventions.

Comparative effectiveness research confers a number of advantages that can potentially improve STEMI care in a cost-effective way. Since this primary PCI registry is performed in a real world setting, across an entire state, the registry will include patient subgroups that are often under-represented in randomized controlled trials. Well researched differential treatment effects across subgroups could help improve patient care delivery, by tailoring therapies to each individual, using the most relevant and appropriate evidence for each patient.<sup>12</sup>

The Primary Angioplasty Registry of Kerala is designed to comply with the reporting standards laid down by the STROBE guidelines.<sup>13</sup>

Even as primary PCI is being increasingly offered as a reperfusion strategy for patients presenting with STEMI in India,<sup>14,15</sup> contemporary STEMI in-hospital mortality continues to be unacceptably high (10.8% in HP registry, 8.2% in Kerala ACS registry).<sup>5,16</sup> And a significant proportion of those who survive suffer from severe left ventricular systolic dysfunction and continue to remain at high risk for heart failure hospitalization and sudden cardiac death.<sup>17</sup> There are large variations in the use of primary angioplasty for patients presenting with STEMI, ranging from 0.9% in the northern Indian state of Himachal Pradesh to 14% in government hospitals in the Southern Indian states of Kerala, and reaching up to 53.3%–60.6% in tertiary hospitals in Tamil Nadu.<sup>7,16,18,19</sup> There are single center reports, mainly from Southern India, reporting an in-hospital mortality rate of 4.2%–5.2%, among Indian STEMI patients undergoing primary PCI.<sup>7,20</sup> But looking at the data from a large volume government hospital in Kerala, the relatively lower mortality in the primary PCI group (5.2%) is accompanied by a doubling of the mortality rate in thrombolysed patients (11.2%), suggesting that the sicker patients were either not offered or did not opt to undergo primary PCI.<sup>7</sup> The mortality benefit of PPCI compared with thrombolysis in STEMI patients is minimal, in the low- and intermediate-risk patients.<sup>21</sup> In the Belgian STEMI registry after adjustment for differences in baseline risk profile, a significant mortality benefit was only present in the high-risk groups.<sup>21</sup> Hence in a resource-limited setting, primary PCI should be offered to the highest-risk patients rather than just to those with lower risk, in order to achieve a substantial reduction in mortality. So registry data should look at how primary PCI can be offered in a timely fashion to all patients including those who are at the highest risk. Hence demonstrating how some hospitals are able to deliver reperfusion therapy using primary PCI to the highest risk patients and how this improves mortality will enable more hospitals in the community to accept this challenge and necessitate the required administrative changes, including training for the catheterization lab staff and interventionists.

Before the government can fund primary PCI services as the reperfusion therapy of choice to all eligible patients, especially to those living below the poverty line, it is imperative that we demonstrate the feasibility and safety of delivering this service in the Indian setting, within acceptable time limits. The National Infarct Angioplasty Project in the UK demonstrated that primary PCI could be delivered within acceptable timelines, would be cost-effective, and could be delivered to a majority of the population. A project was therefore undertaken in England to transform services from a predominant thrombolysis based reperfusion strategy to one based on primary PCI. There was rapid change and, by 2012–2013, over 95% of eligible patients received primary PCI.<sup>22</sup> Such regional audits will play a decisive role in measuring changes in

strategies, monitoring performance and highlighting the associated improvements in outcomes.<sup>22</sup>

Indian states like Kerala has had a rapid expansion in the number of primary PCI-capable hospitals in the recent past, thereby increasing the population level access to emergency cardiac catheterization services.<sup>23</sup> Primary PCI may be the reperfusion method of choice for a large proportion of Indians living in urban and suburban areas, with access to emergency cardiac catheterization services. Indian patients with STEMI present late after the onset of symptoms. In the CREATE registry, the median time from onset of symptoms to arrival at the hospital was 5 h.<sup>8</sup> In the Kerala ACS registry 41.2% of patients arrived at the hospital >6 h after the onset of symptoms.<sup>5</sup> Mortality rates after thrombolysis and PPCI are quite comparable, if both procedures are performed within the first 2 h from symptom onset. Afterwards, mortality increases dramatically after thrombolysis, whereas there is only a modest increase of mortality over time with PPCI.<sup>24</sup> This might be explained by the fact that successful PPCI immediately leads to optimal recanalization (TIMI-3 flow) in >90% of patients, whereas thrombolysis is less effective on 'older' clots, resulting in a TIMI-3 flow rate of ≤50%.<sup>24</sup> A pharmaco-invasive strategy, ideally utilizing pre-hospital thrombolysis, is best suited for geographies in which patients present or call early (within 3 h).<sup>25,26</sup> In the STEPP-AMI study, a prospective observational multicenter pilot study to assess the feasibility of a pharmaco-invasive approach to reperfusion of STEMI in the Indian setting, there was a much higher, though non-significant, adverse event rate with the pharmaco-invasive strategy as compared to a primary PCI strategy (11.1% versus 3.9%). It is likely that this difference did not achieve statistical significance due to the small sample size of this study. In Kerala, the rates of pre-hospital ambulance transfer of patients are very low and there are limited existing organized systems of transfer of STEMI patients between the largely fragmented health care providers.<sup>5,27</sup> The cost effectiveness of a pharmaco-invasive strategy for STEMI is yet to be ascertained in the Indian context, where many centers are doing primary angioplasty using the modest funds offered by state government health schemes in the Southern states.<sup>15</sup> We have to identify geographies in India where the population has adequate access to catheterization labs and designate primary PCI as the preferred mode of reperfusion in these areas.

### 3.1. Procedural variations and cost reduction

The PARK will identify pre-specified procedural variations in interventional techniques and assess how these variations impact patient outcomes. These pre-specified variables include the choice of vascular access, the use of thrombus aspiration, the choice of drug eluting stents with particular reference to the use of indigenous stents, the strut thickness of the DES, and finally the use of routine post-dilatation. The PARK and TRUST Outcomes registries include patients who underwent primary PCI both before and after the 2015 ACC/AHA/SCAI focused update for primary percutaneous intervention for patients with STEMI was published.<sup>28</sup> Thus this study is in a unique position to capture trends in the use of thrombus aspiration and identify if there is a change in the primary clinical endpoint in centers where there is a change in the frequency of use of thrombus aspiration. Observational studies have suggested that stent post-dilatation in STEMI patients undergoing angioplasty and stent implantation is associated with adverse clinical outcomes.<sup>29</sup> However, other studies have suggested that post-dilatation does not have detrimental effects on either angiographic results or on long-term clinical outcomes.<sup>30</sup> Hence it is important to evaluate if it is really necessary, in a resource-limited setting, to use routine post-dilatation following stent implantation in primary PCI.

PARK is intended to serve as a framework for creating a perpetual data collection and feedback system to attain quality improvement in STEMI care in India. An ideal data collection system should be low cost, easy to document and should merge seamlessly with the documentation systems currently employed by participating hospitals. In addition, such a registry would serve as a platform for registry-based clinical trials. Moreover, the results of this registry would help identify the thrust areas where appropriate quality improvement initiatives ought to be implemented, in order to achieve better patient outcomes.

### 3.2. Limitations and challenges

While every effort was made to include all the primary PCI-capable hospitals in the registry, non-participation of a few hospitals could indicate a bias. Hence hospitals participating in the registry may not be representative of the entire state. Since patients in India present late after STEMI,<sup>5</sup> the sicker patients may have died before reaching the PCI-capable hospital and the study population may thus include only relatively lower risk patients. Channeling bias, or selective use of therapies may result in sicker patients receiving different therapies compared to those who are clinically stable. Health insurance coverage in Kerala is inadequate. Financially poor patients are more likely to select thrombolysis as the preferred reperfusion strategy, instead of primary PCI. Such patients may delay accessing STEMI reperfusion facilities due to various socio-cultural reasons. This can potentially result in a selection bias, where the patients undergoing primary PCI may experience much better outcomes, compared to the poorer patients who opt for thrombolysis. Nevertheless, this registry would serve as an important tool for quality assurance regarding the standards of STEMI care in India.

## 4. Conclusions

The primary angioplasty registry of Kerala will serve as a high-quality tool to generate standardized data regarding patient characteristics, procedural variations, adherence to guideline-directed medical therapies and outcomes in individuals undergoing primary PCI for STEMI in India. This important initiative can yield valuable epidemiological insights that can form the basis of quality improvement programs and future clinical trials.

### Conflicts of interest

None.

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