Delivering a STEMI System of Care

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Disclosure Statement of Financial Interest

I, Thomas Alexander, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.
Estimate (Guesstimate) of STEMI in India

- US data from Worcester MA – 1,210 to 770 per million from 1997 to 2005

- European data - 750 to 1,250 per million

- India – 1,500 to 2,000 STEMI per million
  - Over 2.0 – 2.6 million patients with STEMI yearly
CREATE Registry

THE LANCET

A 4-year (2001-05) prospective registry study
- 89 centres from 10 regions and 50 cities in India

- 20,468 patients with ACS of which 12,405 had a STEMI
  - 34% of STEMI were below 50 years
  - 58.5% received thrombolytic and 8% PPCIs
  - Median time from symptoms to hospital was 360 (range 123-1317) minutes
  - Only 4% travelled by ambulance
  - Most patients pay directly for treatment

Kerala ACS Registry

- 25,748 patients – 2007 to 2009 in 125 hospitals
  - 37% of ACS presented as STEMI
  - Age of presentation 60.4 years
  - Symptom onset to presentation > 6hrs in 41% patients
  - 41.4% received thrombolytic and 12.9 % PPCIs
  - 8.2% in-hospital mortality
Coronary Reperfusion

### Interventions in Acute MI

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No of Primary PCI</td>
<td>14,271</td>
<td>20,541</td>
<td>21,343</td>
<td>24,375</td>
<td>41,057</td>
<td>78,859</td>
</tr>
<tr>
<td>% of Total Interventions</td>
<td>12.15%</td>
<td>13.49%</td>
<td>12.04%</td>
<td>17.04%</td>
<td>16.50%</td>
<td>17.58%</td>
</tr>
</tbody>
</table>

*Source: Interventional Council of India*

### Lytic Use Data

<table>
<thead>
<tr>
<th>Lytic</th>
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</thead>
<tbody>
<tr>
<td>Streptokinase</td>
<td>275,000</td>
</tr>
<tr>
<td>Tenecteplase</td>
<td>36,000</td>
</tr>
<tr>
<td>Reteplase</td>
<td>30,000</td>
</tr>
</tbody>
</table>

*Source: Industry*
Access to STEMI Care – Socioeconomic strata

<table>
<thead>
<tr>
<th>Treatments by SocioEconomic Status (SES)</th>
<th>Rich</th>
<th>UMC</th>
<th>LMC</th>
<th>Poor</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombolysis</td>
<td>61%</td>
<td>65%</td>
<td>63%</td>
<td>52%</td>
<td>*</td>
</tr>
<tr>
<td>Cor Angio</td>
<td>41%</td>
<td>36%</td>
<td>22%</td>
<td>9%</td>
<td>*</td>
</tr>
<tr>
<td>PCI</td>
<td>15%</td>
<td>13%</td>
<td>6%</td>
<td>2%</td>
<td>*</td>
</tr>
<tr>
<td>CABG</td>
<td>8%</td>
<td>5%</td>
<td>2%</td>
<td>1%</td>
<td>*</td>
</tr>
<tr>
<td>Antiplatelet</td>
<td>97%</td>
<td>98%</td>
<td>98%</td>
<td>98%</td>
<td>*</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>59%</td>
<td>61%</td>
<td>62%</td>
<td>50%</td>
<td>*</td>
</tr>
<tr>
<td>Lipid lowering</td>
<td>61%</td>
<td>59%</td>
<td>54%</td>
<td>36%</td>
<td>*</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>63%</td>
<td>57%</td>
<td>57%</td>
<td>54%</td>
<td>*</td>
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</tbody>
</table>

Mortality by SES

<table>
<thead>
<tr>
<th>Death rate (un-adjusted)</th>
<th>Rich</th>
<th>UMC</th>
<th>LMC</th>
<th>Poor</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death rate</td>
<td>5.5</td>
<td>5.9</td>
<td>6.5</td>
<td>8.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>(adj-RFs)</td>
<td>5.1</td>
<td>5.9</td>
<td>6.7</td>
<td>7.8</td>
<td>0.0093</td>
</tr>
<tr>
<td>Death rate (adj-RF+Trt)</td>
<td>6.9</td>
<td>7</td>
<td>6.5</td>
<td>6.7</td>
<td>0.9487</td>
</tr>
</tbody>
</table>

Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data

Denis Xavier, Prem Peik, PJ Devaser, Changhua Xu, D Prabhakaran, S Srihari Reddy, Rajeer Gupta, Prashant Joch, Prasvila Khokar, ST Sankarachary, K K Radhakrishnan, V Madhavan, Ruby A, SG Sadasiv, SS Naveen, on behalf of the CREATE registry investigators

Summary

Background India has the highest burden of acute coronary syndromes in the world, yet little is known about the treatments and outcomes of these diseases. We aimed to document the characteristics, treatments, and outcomes of patients with acute coronary syndromes who were admitted to hospitals in India.

Methods We did a prospective registry study in 89 centres from 30 regions and 50 cities in India. Eligible patients had suspected acute myocardial infarction with definite electrocardiographic changes (whether elevated ST [STEMI] or non-STEMI or unstable angina), or had suspected myocardial infarction without ECG changes but with prior evidence of ischaemic heart disease. We recorded a range of clinical outcomes, and all-cause mortality at 30 days.

Findings We enrolled 28,937 patients. Of the 20,468 patients who were given a definite diagnosis, 12,405 (60-6%) had STEMI. The mean age of those patients was 57.5 (CI 12-1.1) years; patients with STEMI were younger (56.3 [12.1] years) than those with non-STEMI or unstable angina (59.3 [11.1] years). Most patients were from lower middle class.
Agenda

- STEMI in India - Challenges
- The STEMI India Model
- The TN STEMI Pilot Project
- Case Study
- ICMR Dissemination Meeting
- Implementation of the STEMI India Model
- Studies Published
# STEMI India Model

<table>
<thead>
<tr>
<th>Variable</th>
<th>Door to Needle &lt; 30 min</th>
<th>Pharmaco-invasive 3-24 hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of patient symptoms</td>
<td>10 min</td>
<td>10 min</td>
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<tr>
<td>Arrival of patient at hospital / ambulance</td>
<td>EGC</td>
<td>Lysis</td>
</tr>
<tr>
<td>Transport to PCI capable Hospital</td>
<td></td>
<td>Cath Lab to Balloon</td>
</tr>
<tr>
<td>Variable</td>
<td>10 min</td>
<td>20-30 min</td>
</tr>
</tbody>
</table>

- **Door to Balloon < 90 min**
- **Total Ischemia Time < 120 min**

*Dr Thomas Alexander*
The STEMI India Model

- Cluster created
  - Hub-and-spoke model

- Linkages built on
  - Electronic Data Communication
  - Management Protocols
  - Insurance reimbursement
  - Dedicated EMS Network

**Hospital Classification**

- HUB A/B: PCI-capable
- SPOKE C: ECG capable <30 mins from HUB
- SPOKE D: ECG & Thrombolysis capable >30 mins from HUB
Key elements

Diagnosis through the STEMI Kit

Appropriate Treatment Strategy
4 Key Aspects

- **Technology**
  - to ensure data entry, remote diagnosis and correct treatment strategy via algorithm

- **Ambulance Network – GVK EMRI – 11000 ambulances**
  - To give all patients access and facilitate inter-hospital transfers

- **Software**
  - To enable data storage on the cloud and ensure optimum treatment strategy via pre-programmed algorithm

- **State-wide Insurance Scheme**
  - To ensure that all patients – especially the poor and disadvantaged can benefit
  - For e.g., the Tamil Nadu Chief Minister’s Comprehensive Health Insurance Scheme was modified
  - Special Categories opened specifically for the STEMI Program to cover thrombolysis, Primary PCI as well as Pharmaco-invasive methods
  - Participating hospitals green-channelled
ECG Device

- ECG can be done at the point of first medical contact

- ECG recorded on the handheld device and transmitted from EMRI ambulance / spoke hospitals to the Hub hospital and the STEMI coordinating centre.

- ‘On Call’ cardiologist to read ECG and confirm STEMI before transportation to STEMI hospital
STEMI Device
Monitoring Device

- Same device becomes a monitoring device
- ABP, SpO2, HR and Cardiac Rhythm
- Automatic transmission to the destination hospital at 5 minute intervals and whenever abnormality detected
Data Entry Device

- Patient data entry can be at any patient access site
  - Ambulance
  - STEMI hospital.

- Data record can be seamlessly accessed and continued during patient care at any of the transfer sites

- STEMI work flow process integrated with specific management protocols and depends on
  - Location of patient
  - Location of closest STEMI hospital
  - Patient clinical condition
    - fibrinolytic contraindications
    - cardiogenic shock
## Agenda

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<tr>
<td>STEMI in India - Challenges</td>
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<tr>
<td>Implementation of the STEMI India Model</td>
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<tr>
<td>Studies Published</td>
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</table>
4 Clusters

- Madras Medical Mission Hospital
  - Metro Specialty hospital
- Stanley Medical College Hospital
  - Tertiary care Government hospital
- CMC Vellore
  - Rural tertiary care hospital
- Kovai Medical Centre and Hospital
  - Urban specialty hospital

The TN STEMI Pilot Project

A System of Care for Patients With ST-Segment Elevation Myocardial Infarction in India
The Tamil Nadu-ST-Segment Elevation Myocardial Infarction Program

Thomas Alexander, MD; Ajit S. Mulickattil, MD; George Joseph, MD; Kumaran Kannan, MD; Ganesh Venkateswaran, MPH; Suma M. Victor, DNB; Carol Ayres, MS; Vijay Samuel Thomson, MD; Vigneshkumar Subbian, MD; Justin Paul Gnanaraj, MD; Jagat Narula, MD, PhD; Dharam J. Kumbhani, MD, SM, MRCP; Brahmsajeet K. Naikamothu, MD, MPH

[Map of India showing locations of hospitals]
Enrolments

Total Enrolments: 898
Pre-Implementation

Total Enrolments: 1522
Post-Implementation

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Figure. Rates of Reperfusion Therapy and Percutaneous Coronary Intervention (PCI) Among Patients With ST-Segment Elevation Myocardial Infarction (STEMI) During the Preimplementation and Postimplementation Phases

A. All patients

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation</th>
<th>Postimplementation</th>
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<tbody>
<tr>
<td>All Reperfusion</td>
<td>100</td>
<td>75</td>
</tr>
<tr>
<td>Thrombolytic-Only Reperfusion</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>Coronary Angiography</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>All PCI</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>Pharmacoinvasive Strategy</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Primary PCI or Pharmacoinvasive Strategy</td>
<td>25</td>
<td>25</td>
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</table>

B. Patients presenting to spoke hospitals

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation</th>
<th>Postimplementation</th>
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</thead>
<tbody>
<tr>
<td>All Reperfusion</td>
<td>100</td>
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<td>25</td>
</tr>
<tr>
<td>Primary PCI or Pharmacoinvasive Strategy</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

Rates of reperfusion and PCI in all patients and those presenting to spoke hospitals in the preimplementation and postimplementation phases.

\( a \quad p = .21 \)

\( b \quad p < .001 \)

\( c \quad p = .23 \)
Mode of Payment – Post Intervention
Overall, A and D Hospitals

<table>
<thead>
<tr>
<th>Hospitals</th>
<th>Total Patients</th>
<th>Private Insurance</th>
<th>Self Payment</th>
<th>State BPL Insurance</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Hospitals</td>
<td>1535</td>
<td>94 (6.1%)</td>
<td>4 (0.3%)</td>
<td>747 (48.7%)</td>
<td></td>
</tr>
<tr>
<td>A Hospitals</td>
<td>958</td>
<td>75 (7.8%)</td>
<td>75 (7.8%)</td>
<td>337 (35.2%)</td>
<td></td>
</tr>
<tr>
<td>D Hospitals</td>
<td>564</td>
<td>15 (2.7%)</td>
<td>15 (2.7%)</td>
<td>211 (37.4%)</td>
<td></td>
</tr>
</tbody>
</table>

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Kaplan-Meier Test

\[ p = 0.0152 \]

Survival Probability

- Pre-Implementation
- Post-Implementation

Months

0  2  4  6  8  10  12  14
## Cost-Effectiveness Analysis

### The TAMIL NADU PILOT PROJECT

2.5 mn people covered across 3 districts

<table>
<thead>
<tr>
<th>District</th>
<th>Population</th>
<th>% covered by the TN Pilot Project</th>
<th>Population covered by the TN Pilot Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coimbatore</td>
<td>3,458,045</td>
<td>6%</td>
<td>207,483</td>
</tr>
<tr>
<td>Vellore</td>
<td>3,936,331</td>
<td>50%</td>
<td>1,968,166</td>
</tr>
<tr>
<td>Chennai</td>
<td>4,681,087</td>
<td>6%</td>
<td>280,855</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12,075,463</strong></td>
<td><strong>6%</strong></td>
<td><strong>2,456,513</strong></td>
</tr>
</tbody>
</table>

* Source: Expert estimates
The TN STEMI Pilot Project

Benefit-Cost Ratio

1,542 life-years saved

Rs. 62 mn saved per year

- Rs. 3.58 economic benefit gained per rupee spent
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Coimbatore Cluster
Mr. P
- 43 year old male
- Smoker (8-10 cig per day)
- Works as a day labourer in a farm
- Has a CM Insurance card

Chest pain on 6.2.2013 at 11:45 am. Taken to a local hospital at Oddanchatram, a spoke hospital 126 km away from the nearest hub hospital with a cath lab in Coimbatore.

Hospital arrival time 12:15 pm. ECG at 12:25 pm and transmitted to hub hospital.
STEMLI confirmed at 12:35 pm.
Thrombolysis and transfer

- Thrombolysis initiated at 12:45pm and completed at 1:45pm
- Post lysis ECG at 3:15pm and transmitted to hub hospital
- Stabilised and transported in a monitored ambulance to hub hospital at Coimbatore 126 km away
- Start transportation at 6:00pm
Arrival at Hub Hospital

- Mild pain persisting on arrival at the hospital at 9:50 pm
- Decision made to transfer patient to the cath lab
- Cath lab activated at 10 pm
Cath Lab

- Radial access
- Cath started at 10:30pm
Case Study

Cath Lab

- Procedure completed at 10:45pm
Patient Discharge

- Discharged on the 8th

- Total bill paid by the state insurance
The TN Pilot Project: First EMRI Pick Up

- Mr. V
  - 51-year-old smoker

- On the 19th of July:
  - 4:00 am Onset of chest pain
  - 5:00 am EMRI 108 called
  - 5:20 am EMRI arrival at scene
  - 5:29 am ECG taken
  - 5:30 am Departure from scene
  - 5:34 am STEMI confirmed by Hub hospital cardiologist
  - 6:10 am Patient arrival at D (Spoke) Hospital
The TN Pilot Project: First EMRI Pick Up

- ECG taken in the ambulance at 5:29 am
The TN Pilot Project: First EMRI Pick Up

- 6:15 am Thrombolysis initiated
- 7:15 am Thrombolysis completed
- 9:54 am Post lysis ECG showed failed thrombolysis

- 11:15 am EMRI called and IFT started
- 2:20 pm Arrival at Hub hospital (KMCH, Coimbatore)
The TN Pilot Project: First EMRI Pick Up

- **3:10 pm** PCI started
- **3:24 pm** PCI completed
The TN Pilot Project: First EMRI Pick Up

- Patient was doing well and was discharged on 22nd July.
- Could not have afforded to even buy the initial medication.
- Total cost taken care of by the CMCHIS scheme and EMRI.
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Dissemination Meeting on Developing a National STEMI Program

Date
18th January 2018

Venue
National Institute of Pathology, Safdarjung Hospital Campus, Ansari Nagar, New Delhi
Recommendations

- The STEMI India model may be adopted as the National STEMI Programme.

- As STEMI India has unique competencies to run similar programs in other states, it would therefore be the ideal organisation to be the implementing agency in each state, either wholly or in partnership with the state government. A customised Project Implementation Plan can be drawn up for each specific state. The detailed/specific modalities can be worked by STEMI India based on requirements of the state.

- STEMI India may be contacted by states for providing app for geographical mapping, facility mapping etc. Once mapping is done by the state, data may be provided by states to STEMI India in the prescribed format for developing a state-specific STEMI model.
The National Health Mission

FUNDING FOR THE STATE-LEVEL STEMI PROGRAMME
The STEMI Programme as an Innovation

- Up to 10% of the health systems strengthening budget (Mission Flexipool and NUHM) may be proposed for innovations
  - under budget head B.14 for Mission Flexipool and budget head 7 for NUHM.

- The State should upload the justification sheet for the “new activity” in the software with a brief description, rationale, data/background information required to appraise the proposal and budget breakup – will be provided by STEMI India.

- The innovations should have a baseline and must be evaluated after 1 ½ - 2 years’ of implementation – built into the STEMI Programme and can be independently monitored.

Source: Operational Guidelines For PIP 2016-17
Partnerships with the Private Sector

- NHM will encourage the public sector to contract-in or outsource those services which improve efficiency and quality of care in the public hospital.

- These services include …diagnostic services. In cases where the skill sets required are non-clinical but specialized, and high quality cannot be assured because the public health workforce is largely clinical; outsourcing has significant advantages.

- In view of presence of larger number of private (for profit and not for profit) health service providers in urban areas, public – private partnerships particularly with not for profit service providers will be encouraged.

- Clear and monitorable Service Level Agreements (SLAs) need to be developed for engagement with Private Sector. Efforts would be made to explore possible areas where NGOs/ Charitable institutions may bring their expertise and participation.

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<tr>
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</table>
Implementation of the STEMI India Model

Dr. T. Alexander
Dr. A. Mulasari
Roll-out Plan

THE STEMI INDIA MODEL
Implementation of the STEMI India Model

Governance Structure

Steering Committee

with representatives from

- State Government
- Cardiological Society of India (CSI) and Association of Physicians of India (API)
- State Insurance Agency
- State-wide Ambulance Service
- STEMI India
Implementing the STEMI India Protocol

Step I
- Geographical Mapping
- Cluster Mapping
- Identification of hospitals participating in the STEMI Programme

Step II
- Drawing up agreements with Hospitals, EMS Providers and Insurance Agencies
- Hiring and nominating personnel
- Procurement of STEMI Kits

Step III
- Phase 1 – Installation of STEMI Kits, Testing and Initial Training
- Phase 2 – Base-case study
- Phase 3 – Pre-implementation Training
- Phase 4 - Implementation

Step IV
- Project Operation
- Periodic Report Submission
## Timelines

### Implementation Schedule

<table>
<thead>
<tr>
<th>Step</th>
<th>Phase</th>
<th>Activity</th>
<th>Duration in months</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td></td>
<td>Geographical mapping</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cluster mapping</td>
<td>2</td>
</tr>
<tr>
<td>I</td>
<td></td>
<td>Agreements with Hospitals, EMS Services and Insurance Agencies</td>
<td>3</td>
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<tr>
<td></td>
<td></td>
<td>Hiring personnel</td>
<td>4</td>
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<td></td>
<td>Procurement of STEMI Kits</td>
<td>5</td>
</tr>
<tr>
<td>II</td>
<td></td>
<td>STEMI Kit installation, verification of connectivity</td>
<td>6</td>
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<td></td>
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<td>Initial Training</td>
<td>7</td>
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<tr>
<td>III</td>
<td>1</td>
<td>Base-case study - data collection and verification</td>
<td>8</td>
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<td></td>
<td>2</td>
<td>Pre-implementation Training</td>
<td>9</td>
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<td>3</td>
<td>Implementation phase - project online</td>
<td>10</td>
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<td>4</td>
<td>Project Operation</td>
<td>11</td>
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STELMI India Projects

Sources:
http://www.census2011.co.in/district.php
https://gramener.com/indiamap/

<table>
<thead>
<tr>
<th>State/District</th>
<th>Population</th>
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<tr>
<td>Goa</td>
<td>1,458,545</td>
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<td>Medak</td>
<td>3,033,288</td>
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<tr>
<td>Gulbarga, Karnataka</td>
<td>2,566,326</td>
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<tr>
<td>Kurnool, Andhra Pradesh</td>
<td>4,053,463</td>
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<td><strong>Total</strong></td>
<td><strong>11,111,622</strong></td>
</tr>
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Agenda

- STEMI in India - Challenges
- The STEMI India Model
- TN STEMI Project
- Case Study
- ICMR Dissemination Meeting
- Implementation of the STEMI India Model
- Studies Published
Systems of care for ST-elevation myocardial infarction in India: is it time?
Thomaz Alexander, Samani Mehta, Ajit Muluk, Dr Ramesh P. Nallamothu

ABSTRACT

Objectives: There is limited evidence on the systems of care for STEMI systems in India. This study examined whether the STEMI systems in India have developed in accordance with the WHO guidelines for STEMI systems in India.

Methods: The study was a retrospective analysis of the data collected from the Indian Society for Cardiac Care (ISCC) registry for the year 2011.

Results: The study revealed that the STEMI systems in India are not in accordance with the WHO guidelines. The systems in India are characterized by a low level of evidence, a lack of standardization, and a high level of disparity.

Conclusions: The systems of care for STEMI in India need to be improved to ensure effective and equitable care for patients with STEMI.

Developing a STEMI System of Care for Low- and Middle-Income Countries
The STEMI India Model
Thomas Alexander, Ajit S. Muluk, Annalaxmi

BMJ Open
Protocol for a prospective, controlled study of assistive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu: the TN-STEMI programme
Dr Thomas Alexander

Available online at www.bmj.com | Published by bmjgroup.com

2011
2013
2014
2015

Report on the 2011 JAMAI Cardiology Original Investigation
A System of Care for Patients With ST-Segment Elevation Myocardial Infarction in India
The Tamil Nadu–ST-Segment Elevation Myocardial Infarction Programme
Thomaz Alexander, Ajit S. Muluk, George Joseph, N. Ramesh Kumar, Meenakshi V. Nair, Ganesh Venkataram, MPH, Sumai M. Victoria, MD, Colby Ayres, MD, Vipj Samuel Thominson, MD, Vijayalakshmi Subbian, MD, Justin Paul Gnanraj, MD, Jagat Jhund, MD, PNC, Dhiran J. Kumbharam, MD, SW, MICP, Shrinivas K. Nallamothu, MD, MPH

CITE Forum: Consensus Statement
Framework for a National STEMI Program: Consensus document developed by STEMI INDIA, Cardiological Society of India and Association of Physicians of India

Dr Thomas Alexander
Thank you