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A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu

The TN-STEMI Programme

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For TN-STEMI Programme Investigators

Abstract

Introduction: Over the last two decades, India has witnessed a staggering increase in the incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher rates of STEMI and younger populations that suffer from it when compared with developed countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary intervention (PCI) are available to only a minority of patients. This gap in care is a result of financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of acute medical services for a majority of its population.

Methods and analysis: Encouraged by the results of the previously conducted 'Kovai-Erode STEMI pilot study,' we designed the current prospective study which will study whether or not optimal and timely reperfusion therapy can be delivered to high-risk patients in India. Novel aspects of this study involve: creating integrated networks of facilities across the state of Tamilnadu; leveraging newly-developed ambulance and emergency medical services; incorporating recent state insurance schemes for vulnerable populations to broaden access;

and combining innovative, "state-of-the–art" information technology platforms with existing hospital infrastructure.

Ethics: This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the Indian Council for Medical Research. All participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants.

Dissemination and results: Our findings will be reported through scientific publications, research conferences, and public policy venues aimed at state and local governments in India. If successful this model can be extended to other areas of India as well as serve as a model of STEMI systems of care for low-and-middle income countries across the world.

Registration: Trial is registered with Clinical trial registry of India, No: CTRI/2012/09/003002.

Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays. Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach. Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it demonstrated that by linking several smaller, peripheral “spoke” hospitals with a centrally-located, PCI-capable “hub” hospital, the use and timelines of reperfusion therapy could be improved. Encouraged by these results, we now propose a broader ‘hub and spoke’ model in

other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to describe the framework and methods associated with this programme – the first-ever, multi-centre study that aims to improve delivery of reperfusion therapy in India. If successful, this programme can be extended to other areas of the country and serve as a model of STEMI systems of care for low-and-middle income countries.

Methods & Analysis

Study design and objectives

The TN- STEMI programme is a prospective, multi-centre study that has been planned as a community-based treatment programme for improving use and timeliness of reperfusion therapy in patients diagnosed with STEMI as confirmed by an ECG. It involves a stepwise approach that facilitates rapid and definitive restoration of coronary blood flow using a combination of pharmacological and mechanical reperfusion therapies based on the presentation of the patient. This programme will use a 'hub-and-spoke' model that relies on an integrated healthcare network based on clusters of primary-care health clinics and small hospitals built around 4 large tertiary-care facilities that are capable of providing advanced cardiovascular services, including PCI and cardiac surgery. The primary objectives of the TN-STEMI programme is to use organized systems of care to: (1) improve the use of reperfusion therapy and reduce the time from first medical contact to device or drug in STEMI patients; and (2) increase rates of early invasive risk stratification in eligible patients.

We plan to measure our ability to achieve this overall objective through explicit measurement of changes in processes of care before and after introduction of the TN STEMI programme. Secondary (and implicit) objectives include:

- Integrating care between emergency medical services (EMS) and acute-care clinics and hospitals at the community level in India, especially in rural areas.

- Providing a pragmatic model to understand the challenges associated with developing a national STEMI programme in India.
- To increase public awareness of appropriate STEMI care in India

Study population, facilities and enrolment period

The TN-STEMI programme incorporates an inclusive, "all-comers" study design. Consecutive patients aged 20 years or older with symptoms or signs consistent with acute coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the study, an ECG must have evidence of myocardial injury showing ≥ 1-mm ST-segment elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR), ≥ 1-mm ST-segment elevation in a precordial lead V4 through V6, ≥ 2-mm ST-segment elevation in V1 through V3 or a new left bundle branch block.

Both "hub" hospitals and "spoke" hospitals are included in each of the 4 clusters. The hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals situated within 30 minutes of a hub hospital have been classified as class C while those beyond 30 minutes were class D hospitals. All participating units had to commit to complying with the study protocol and were required to be within the catchment area for available emergency ambulance services. Details of the hub-and-spoke model are discussed below.

Baseline data on management and outcomes of STEMI patients will be collected for 3 months at all the participating hospitals during an enrolment period that started in the fall of 2012. The enrolment period will be "rolling" for each of the hospitals and followed by 9

months of post-implementation data collection on STEMI patients after execution of the TN-STEMI programme. Outcomes that we will be evaluating are discussed in detail below and include data on processes of care that will be available during the hospitalization and follow up data for one year from the index event; the 1 year follow up will either be a hospital visit, if it is the routine practice at the local site or a telephonic follow up if hospital visit is not required by the treating hospital. Estimated loss to follow up is 20%.

TN-STEMI programme: the hub and spoke model

We have organized the network of hospitals within the TN-STEMI programme using a "hub-and-spoke" model that recognizes four classes of healthcare facilities that care for STEMI patients in India:

- **Class A Hospital -** Class A hospitals are PCI-capable hospitals with healthcare teams available 24/7 for managing STEMI and its complications. Patients admitted to these hospitals typically undergo primary PCI with an aim of door-to-balloon time less than 90 minutes.
- **Class B Hospital -** These are PCI-capable hospitals, but primary PCI cannot be performed outside of working hours. Patients admitted to a class B hospital outside of working hours are typically are treated with fibrinolysis with a goal of door-to-needle time less than 30 minutes. Patients would be taken for catheterization within the next 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives during working hours.
- **Class C Hospital –** These are healthcare facilities and hospital with the capability to perform and transmit ECGs *and* that are located within 30 minutes of a Class A or Class B hospital. All Class C hospitals would constitute the spokes of the Class A/B

hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital. This process of transfer should ideally take less than 60 minutes.

- **Class D Hospital -** This class of healthcare facilities and hospitals have the capability to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable hospital. All of these are capable of providing fibrinolysis. All Class D hospitals would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D hospital are treated with fibrinolysis after confirmation of STEMI as per routine hospital practice. After informing the receiving hospital that is linked to it, transfer of the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated PCI, within the next 3 to 24 hours.

Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D hospitals. A full list of the participating hospitals organized by their classes is presented in Table 1. Figure 1 shows the "hub-and-spoke" model; Figure 2 shows a geographical map of Tamilnadu State showing locations of clusters of "hub-and-spoke" hospitals in the TN-STEMI programme.

Key partners in TN-STEMI programme

The TN-STEMI programme involves 3 key partners from both the public and private sectors:

1. **Government of Tamilnadu – Chief Minister's Health Insurance Scheme.** A recent and important development that is relevant to the TN-STEMI programme in India has been the establishment and growth of government-sponsored social insurance coverage for healthcare among those below the poverty line. This has been a state-based development, including the Chief Minister's Health Insurance Scheme in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this programme. This requirement will ensure that patients from all social classes can

receive timely and suitable treatment for STEMI with no out-of-pocket expenses incurred for their hospitalization. The Chief Minister's Health Insurance scheme is currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari TTK Healthcare, MediAssist and MD India Third Party Administrator.

2. **EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and Research Institute (GVK-EMRI) operates as a public-private-partnership and is recognized as a not-for-profit entity. It is an organization that has pioneered the development of emergency medical services (EMS) in India, including training paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI ambulance services may be activated by a patient with chest pain or a healthcare facility using the" Call 108" system. Units within this EMS are capable of acquiring ECGs, transmitting ECGs to an 'on call cardiologist' for STEMI confirmation, locating the nearest PCI-capable hospital using GPS provided by a coordinating centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances will also transport patients from the spoke hospital to the hub hospitals after initial evaluation and possible treatment**.**

3. **STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in India led by physicians from across the country. The purpose of this organization is to review and disseminate the latest information from across the world on STEMI management to providers involved in STEMI care in India; to help organize and train STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the context of healthcare systems' needs and resources in India. Other goals include: facilitating and contributing to national STEMI guidelines within India and improving public education to reduce delays in accessing care. The organization's role in the TN-STEMI programme has been to provide expertise in the development and

oversight of the study protocol to meet standards of care within India for STEMI patients.

In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and Maestro technologies, to coordinate the development of novel software and hardware (described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved with the clinical administration of the trial. The TN-STEMI programme is supported by an independent grant from the Indian Council for Medical Research (ICMR).

STEMI Technology

A novel aspect of the TN-STEMI programme is the implementation of new hardware and software components to optimize the performance and transmission of ECGs and other clinical information across the network of hospitals in India by paramedics, nurses and physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:

1. ***ECG recording device*** - ECG devices will record the patient's ECG which would then be transmitted by paramedics to a hand held device of the STEMI coordinator in a hub hospital.
2. ***Vital signs monitoring device*** - This device will record the patient's vital signs and hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure, heart rate and rhythm strip. This will also permit the transmission of key information by paramedics to STEMI coordinators at hub hospitals.
3. ***Display and transmitting device*** - Each STEMI coordinator will have a hand held device which collects and transmits data when required with sufficient battery support. This will allow for communication between STEMI coordinators and on-call cardiologists at the Class A/B hospitals.

Coordination of the hardware units by paramedics, STEMI coordinators and on-call cardiologists will be performed through unique software applications that are specifically designed for the TN-STEMI programme to be used across a universal platform for multiple devices. These are summarized in the Appendix.

The paramedic and STEMI coordinators will capture the patient demographic details along with a checklist for eligibility for fibronolytic therapy. This information along with the ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and decide on initial treatment. The on-call cardiologist receives an alert once these data are obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in turn alerts the paramedic to transport the patient to the destination based on global positioning system (GPS) navigation. A dedicated server will be available round the clock to route all information from one hand held device to the other in ambulance or hospital. Data are simultaneously stored on the server along with the ECG snapshot which can be accessed by teams at the receiving hospital.

Treatment Protocols

There will be two strategies to manage STEMI patients and both are adapted from current American College of Cardiology/American Heart Association and European Society of Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall, these guidelines intend to minimize the total ischemic time (7).

1. *Primary and Rescue PCI:* All patients with STEMI presenting to a Class A hospital, Class B hospital during working hours, and Class C hospital with an estimated transportation time of less than 60 minutes will undergo primary PCI. The aim is to achieve a door-to-balloon time of less than 90 minutes and a first medical contact to balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a

spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed reperfusion (i.e., rescue PCI).

2. *Pharmacoinvasive Strategy:* All patients with STEMI presenting to a Class B hospital outside of working hours or Class D hospital with anticipated long transportation times, unless contraindicated, will receive fibrinolysis as per routine hospital practice with goal of door-to-needle time less than 30 minutes. Patients will then be transferred for an early invasive strategy with coronary angiography and PCI, if indicated, within 3 to 24 hours of receiving fibrinolytic therapy.

All other medical therapy will be at the discretion of the treating physician and the healthcare team. However, the use of immediate dual antiplatelet therapy and anticoagulation with heparin or equivalent drugs is encouraged. Other therapies, such as morphine, nitroglycerin, beta-blockers and calcium-channel blockerse, are not standardized.

All participating units will have a single protocol in place for reperfusion therapy and cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on distance, logistics, resources and equipment availability. STEMI kits consisting of 'Operations Manual and Guidelines for Management at First Medical Contact' will be circulated. These operations manual detail the interventional strategy at each point of care: the ambulance, the emergency department, inter-hospital transfer, and the role of the hospitals. A STEMI coordinator responsible for accurate management of the project will be identified at each point of system care.

Patients with chest pain who call '108' will enter the system outside of the hospitals. These patients will be picked up by the EMRI ambulance, will have a preliminary ECG performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call

cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist, the ambulance will use GPS to locate the closest hospital in the cluster and re-route the patient there for appropriate treatment. Even before the patient reaches the hospital, the STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital for primary PCI, bypassing a referring hospital even if it is the closest hospital.

Primary and Secondary Outcomes

Our primary outcomes will be based on care provided during the hospitalization and process measures associated with the use of and time to reperfusion therapy. Secondary outcomes will be clinical events that occur during the hospitalization and follow-up, although we recognize that we will be underpowered to detect differences in these events. These are detailed below.

Primary Outcomes

- Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
- Use of timely reperfusion defined as door-to-balloon time ≤ 90 minutes or door-to-needle ≤ 30 minutes in patients with STEMI treated with primary PCI and fibrinolytic therapy, respectively
- Use of early invasive risk stratification with coronary angiography and PCI in patients treated with fibrinolytic therapy

Secondary Outcomes

- Use of rescue PCI in patients with failed fibrinolysis.
- Composite of the following in-hospital outcomes: mortality, recurrent infarction/ischemia, stroke, major and minor bleeds.
- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

Statistical considerations

Data from all centres will be combined for analysis. Data will be **c**ollected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate. Comparison between patients treated during the enrolment period and post-implementation periods based on the study outcomes will be tested using applicable test of hypothesis such as t-test, chi-square test or non parametric tests.

Eligible patients from the study with reference to the definition of control population and intervention population will be used for statistical comparison. Control population is defined as population included prior to implementation of TN-STEMI programme into a cluster that will provide baseline data for evaluation of operational parameters and outcomes before and after the intervention (i.e., the enrolment period). Intervention population as per

protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster into TN-STEMI programme (i.e., the post-implementation period). This will also include patients who were transferred and completed the study protocol, patients who were transferred and did not complete the study prior to intervention and post intervention.

No formal sample size estimation has been done since this is a real-world implementation study, evaluating the relationship between the initiation of this multifaceted intervention and key process measures. The number of patients anticipated to be enrolled in to the study was based on a feasibility assessment and using available (but often limited) hospital statistics. Based on existing information, we have assumed that approximately 300-500 patients with STEMI will be enrolled in each of the clusters in a 1 year period is made. The baseline data will be used to compare the outcome after the implementation phase to measure our study objectives.

Study oversight, ethical considerations, and data collection and quality

This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the ICMR. Despite the fact that this is a implementation study focusing on quality improvement, all participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants. The rights, safety and well-being of the study subjects are the most important considerations and should prevail over interests of society and science.

Data collection and quality control:

Data will be collected prospectively from all the participating units from personnel blinded to the aims of the study. Electronic case report forms (eCRFs) must be completed for each

patient screened/enrolled and the data for this study will be collected with an electronic data capture application. As required by the ICH GCP (International Conference on Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator will allow direct access to all pertinent medical records in order to allow the verification of data gathered in the eCRFs and for the review of the data collection process. Data will be captured and processed into a quality assured database. The investigator(s)/institution(s) will permit study-related monitoring, audits, and regulatory inspection(s), providing direct access to source data documents. Periodic quality check will be done to ensure proper functioning and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement (QI) reports will be generated for every participating hub hospital to ensure that quality systems are in place. QI will include a review of system administration/ organizational activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will periodically review and evaluate the accumulated study data for participant safety, study conduct, study progress, and make recommendations concerning the continuation, modification, or termination of the project.

Discussion

Reperfusion therapy is critical in the management of patients with STEMI and one of the most powerful predictors of early and late survival; however, its use is considerably hampered by several non-clinical and system-related barriers in low-to-middle income countries like India. Furthermore, primary PCI has increasingly become the preferred method of reperfusion therapy in STEMI management but because of the additional resources that it requires it is frequently unavailable in these settings. Expanding population-wide availability

of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects of STEMI systems of care that have been used with great success in Western Europe and North America.

We believe that the TN-STEMI programme will create new opportunities to deliver these therapies in India by addressing various clinical, logistical and societal factors. As in other countries, effective management of STEMI at the community level in India will require executing proven treatment protocols along with efficient and rapid inter hospital transfer within coordinated hospital networks. Regional systems of care such as "Mission: Lifeline" have been successfully used in STEMI management in the US (8). In Europe, 'hub and spoke' model of STEMI networks also demonstrate improved adherence to reperfusion therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-For-Life programme of the European Society of Cardiology. Although STEMI management in India may also benefit from such organized systems of care, there are little or no data to support that these approaches improve key processes of care or outcomes in this environment. Hence, understanding the effect of the STEMI network implemented in the state of Tamilnadu will have substantial implications for the country. This approach is particularly worthwhile as it leverages unique public and private partnerships, technological innovation in monitoring devices, an expanding EMRI ambulance system, and novel strategies for reperfusion therapy and early invasive risk stratification. If successful, this type of network may be extended to the rest of India and even worldwide.

Contributions of authors:

Dr. Thomas Alexander, Dr. Ajit S Mullasari: Conception of trial design and provided the important intellectual content

Dr. Suma M Victor: Drafting of the article

Dr. Ganesh Veerasekar: Drafting of tables and Images

Dr. Kala Subramaniam: Provided the statistical design

Dr. Brahmajee K Nallamothu: Final correction & approval of the version

Disclosures:

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Conflict of interests: The author(s) declare that they have no conflicting interests.

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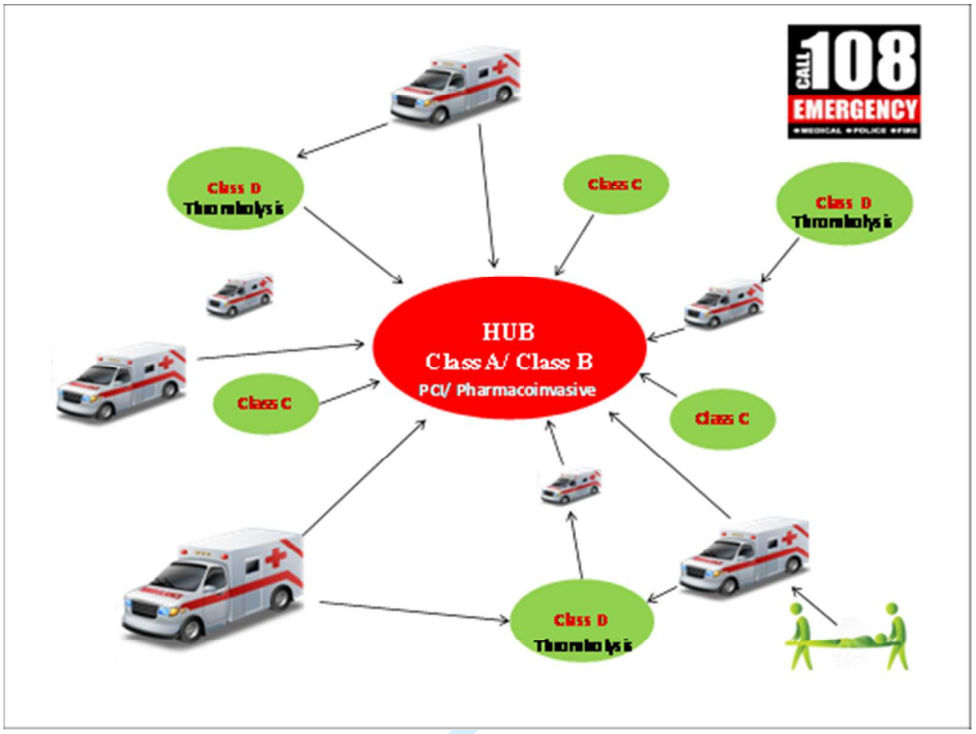

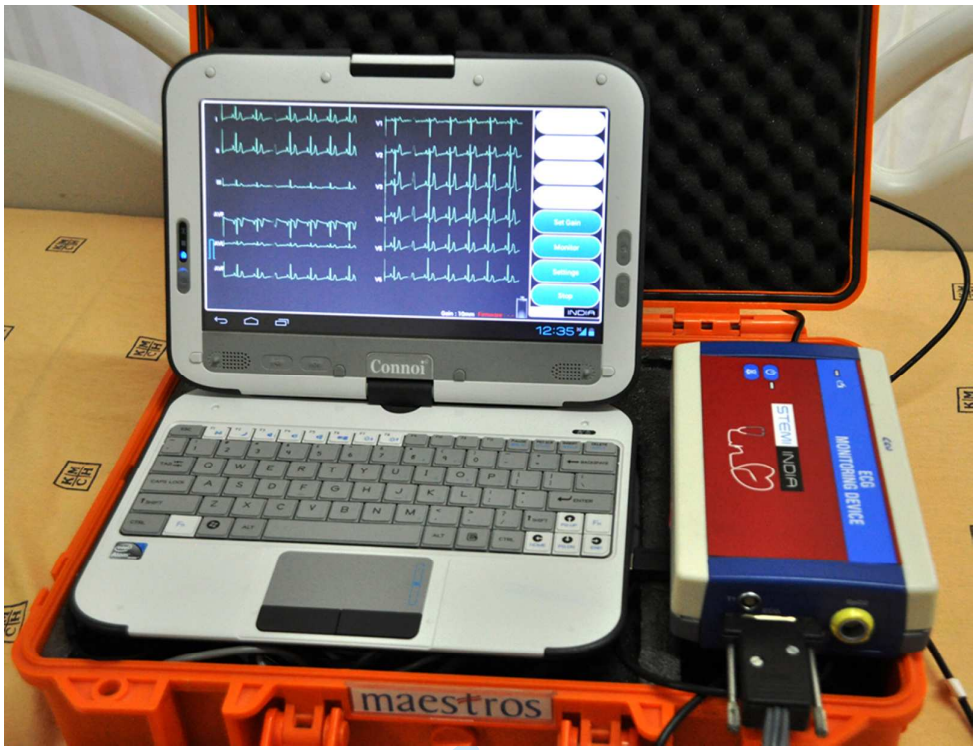

CLUSTER 1:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
CLUSTER 2:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D

	Kanchipuram	
CLUSTER 3:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
CLUSTER 4:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – 'Ice Cream Sandwich' , 2G or 3G connectivity	Android 4.0 –'Ice Cream Sandwich' , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

Table 2: ECG signal specifications:

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

Table 3: Arterial saturation (SaO_2) signal specification:

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO_2 > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

Table 4: Blood pressure (BP) signal specification:

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	 25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.

Table 5: Battery details

Type	Rechargable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

Table 6: Display Device Specifications

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen • 10.1" 1366x768 optional display • Convertible: traditional or touch-optimized tablet mode • Palm-resting feature allows to write and draw comfortably
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN • 3G • GPS
Keyboard/touch Pad	• Water resistant keyboard • Water resistant touch pad (integrated vertical scrolling) • Anti-microbial keyboard
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	• Size including handle: 268mm x (39.5~32mm)

	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

Table 7: Carry case specifications

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS

BMJ open

A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu- The TN-STEMI Programme

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A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu

The TN-STEMI Programme

Thomas Alexander, Suma M Victor, Ajit S Mullasari, Ganesh Veerasekar, Kala Subramaniam, Brahmajee K Nallamothu

For TN-STEMI Programme Investigators

Abstract

Introduction: Over the last two decades, India has witnessed a staggering increase in the incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher rates of STEMI and younger populations that suffer from it when compared with developed countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary intervention (PCI) are available to only a minority of patients. This gap in care is a result of financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of acute medical services for a majority of its population.

Methods and analysis: This is a prospective, multi-centre, "pre test/post test" Quasi-experimental, community-based study. This programme will use a 'hub-and-spoke' model of an integrated healthcare network based on clusters of primary-care health clinics, small hospitals and large tertiary-care facilities. It is an "all-comers" study which will enrol consecutive patients presenting with STEMI to the participating hospitals. The primary objectives of the study is to improve the use of reperfusion therapy and reduce the time from first medical contact to device or drug in STEMI

patients; and to increase rates of early invasive risk stratification with coronary angiography within3 to 24 hours of fibrinolytic therapy in eligible patients through changes in process of care. Outcomes will be measured with statistical comparison made before and after implementing the TN STEMI programme. The estimated sample size is based on the Kovai Erode Pilot study, which provided initial work on establishing this type of programme in South India. It will be adequately powered at 80% with a superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3 clusters. Thus, the enrolment period of 9 months will result in a sample size of 1500 patients.

Ethics: This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the Indian Council for Medical Research. All participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants.

Dissemination and results: Our findings will be reported through scientific publications, research conferences, and public policy venues aimed at state and local governments in India. If successful this model can be extended to other areas of India as well as serve as a model of STEMI systems of care for low-and-middle income countries across the world.

Registration: Trial is registered with Clinical trial registry of India, No: CTRI/2012/09/003002.

Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays. Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach. Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it demonstrated that by linking several smaller, peripheral “spoke” hospitals with a centrally-located, PCI-capable “hub” hospital, the use and timelines of reperfusion therapy could be

improved. Encouraged by these results, we now propose a broader 'hub and spoke' model in other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to describe the framework and methods associated with this programme – the first-ever, multi-centre study that aims to improve delivery of reperfusion therapy in India. If successful, this programme can be extended to other areas of the country and serve as a model of STEMI systems of care for low-and-middle income countries.

Methods & Analysis

Study design and objectives

The TN- STEMI programme is a prospective, controlled, multi-centre pre test/post test Quasi- experimental study that has been planned as a community-based treatment programme for improving use and timeliness of reperfusion therapy in patients diagnosed with STEMI as confirmed by an ECG. It involves a stepwise approach that facilitates rapid and definitive restoration of coronary blood flow using a combination of pharmacological and mechanical reperfusion therapies based on the presentation of the patient. This programme will use a 'hub-and-spoke' model that relies on an integrated healthcare network based on clusters of primary-care health clinics and small hospitals built around 4 large tertiary-care facilities that are capable of providing advanced cardiovascular services, including PCI and cardiac surgery. The primary objectives of the TN-STEMI programme is to use organized systems of care to: (1) improve the use of reperfusion therapy and reduce the time from first medical contact to device or drug in STEMI patients; and (2) increase rates of early invasive risk stratification in eligible patients **by employing a pharmacoinvasive strategy of reperfusion.**

We plan to measure our ability to achieve this overall objective through explicit measurement of changes in processes of care before and after introduction of the TN STEMI programme. Secondary (and implicit) objectives include:

- Integrating care between emergency medical services (EMS) and acute-care clinics and hospitals at the community level in India, especially in rural areas.
- Providing a pragmatic model to understand the challenges associated with developing a national STEMI programme in India.
- To increase public awareness of appropriate STEMI care in India

Study population, facilities and enrolment period

The TN-STEMI programme incorporates an inclusive, "all-comers" study design. Consecutive patients aged 20 years or older with symptoms or signs consistent with acute coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the study, an ECG must have evidence of myocardial injury showing ≥ 1-mm ST-segment elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR), ≥ 1-mm ST-segment elevation in a precordial lead V4 through V6, ≥ 2-mm ST-segment elevation in V1 through V3 or a new left bundle branch block.

Both "hub" hospitals and "spoke" hospitals are included in each of the 4 clusters. The hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals situated within 30 minutes of a hub hospital have been classified as class C while those beyond 30 minutes were class D hospitals. All participating units had to commit to complying with the study protocol and were required to be within the catchment area for

available emergency ambulance services. Details of the hub-and-spoke model are discussed below.

Baseline data on management and outcomes of STEMI patients will be collected for 3 months at all the participating hospitals during an enrolment period that started in the fall of 2012. The enrolment period will be "rolling" for each of the hospitals and followed by 9 months of post-implementation data collection on STEMI patients after execution of the TN-STEMI programme. Outcomes that we will be evaluating are discussed in detail below and include data on processes of care that will be available during the hospitalization and follow up data for one year from the index event; the 1 year follow up will either be a hospital visit, if it is the routine practice at the local site or a telephonic follow up if hospital visit is not required by the treating hospital. Estimated loss to follow up is 20%. **This estimate is based on our experiences with clinical research in these communities and is conservative.**

TN-STEMI programme: the hub and spoke model

We have organized the network of hospitals within the TN-STEMI programme using a "hub-and-spoke" model that recognizes four classes of healthcare facilities that care for STEMI patients in India:

- **Class A Hospital -** Class A hospitals are PCI-capable hospitals with healthcare teams available 24/7 for managing STEMI and its complications. Patients admitted to these hospitals typically undergo primary PCI with an aim of door-to-balloon time less than 90 minutes.
- **Class B Hospital -** These are PCI-capable hospitals, but primary PCI cannot be performed outside of working hours. Patients admitted to a class B hospital outside of working hours are typically are treated with fibrinolysis with a goal of door-to-needle time less than 30 minutes. Patients would be taken for catheterization within the next 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class

of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives during working hours.

- **Class C Hospital –** These are healthcare facilities and hospital with the capability to perform and transmit ECGs *and* that are located within 30 minutes of a Class A or Class B hospital. **These hospitals do not have fibrinolysis capability**. All Class C hospitals would constitute the spokes of the Class A/B hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital, **depending on the availability primary PCI.** This process of transfer should ideally take less than 60 minutes.
- **Class D Hospital -** This class of healthcare facilities and hospitals have the capability to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable hospital. All of these are capable of providing fibrinolysis. All Class D hospitals would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D hospital are treated with fibrinolysis after confirmation of STEMI as per routine hospital practice. After informing the receiving hospital that is linked to it, transfer of the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated PCI, within the next 3 to 24 hours.

Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D hospitals. A full list of the participating hospitals organized by their classes is presented in Table 1. Figure 1 shows the "hub-and-spoke" model; Figure 2 shows a geographical map of Tamilnadu State showing locations of clusters of "hub-and-spoke" hospitals in the TN-STEMI programme.

Key partners in TN-STEMI programme

The TN-STEMI programme involves 3 key partners from both the public and private sectors:

1. **Government of Tamilnadu – Chief Minister's Health Insurance Scheme.** A recent and important development that is relevant to the TN-STEMI programme in India has been the establishment and growth of government-sponsored social insurance coverage for healthcare among those below the poverty line. This has been a state-based development, including the Chief Minister's Health Insurance Scheme in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this programme. This requirement will ensure that patients from all social classes can receive timely and suitable treatment for STEMI with no out-of-pocket expenses incurred for their hospitalization. The Chief Minister's Health Insurance scheme is currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari TTK Healthcare, MediAssist and MD India Third Party Administrator.

2. **EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and Research Institute (GVK-EMRI) operates as a public-private-partnership and is recognized as a not-for-profit entity. It is an organization that has pioneered the development of emergency medical services (EMS) in India, including training paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI ambulance services may be activated by a patient with chest pain or a healthcare facility using the" Call 108" system. Units within this EMS are capable of acquiring ECGs, transmitting ECGs to an 'on call cardiologist' for STEMI confirmation, locating the nearest PCI-capable hospital using GPS provided by a coordinating centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances will also transport patients from the spoke hospital to the hub hospitals after initial evaluation and possible treatment**.**

3. **STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in India led by physicians from across the country. The purpose of this organization is to

review and disseminate the latest information from across the world on STEMI management to providers involved in STEMI care in India; to help organize and train STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the context of healthcare systems' needs and resources in India. Other goals include: facilitating and contributing to national STEMI guidelines within India and improving public education to reduce delays in accessing care. The organization's role in the TN-STEMI programme has been to provide expertise in the development and oversight of the study protocol to meet standards of care within India for STEMI patients.

In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and Maestro technologies, to coordinate the development of novel software and hardware (described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved with the clinical administration of the trial. The TN-STEMI programme is supported by an independent grant from the Indian Council for Medical Research (ICMR).

STEMI Technology

A novel aspect of the TN-STEMI programme is the implementation of new hardware and software components to optimize the performance and transmission of ECGs and other clinical information across the network of hospitals in India by paramedics, nurses and physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:

1. ***ECG recording device*** - ECG devices will record the patient's ECG which would then be transmitted by paramedics to a hand held device of the STEMI coordinator in a hub hospital.
2. ***Vital signs monitoring device*** - This device will record the patient's vital signs and hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure,

heart rate and rhythm strip. This will also permit the transmission of key information by paramedics to STEMI coordinators at hub hospitals.

3. ***Display and transmitting device*** - Each STEMI coordinator will have a hand held device which collects and transmits data when required with sufficient battery support. This will allow for communication between STEMI coordinators and on-call cardiologists at the Class A/B hospitals.

Coordination of the hardware units by paramedics, STEMI coordinators and on-call cardiologists will be performed through unique software applications that are specifically designed for the TN-STEMI programme to be used across a universal platform for multiple devices. These are summarized in the Appendix.

The paramedic and STEMI coordinators will capture the patient demographic details along with a checklist for eligibility for fibronolytic therapy. This information along with the ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and decide on initial treatment. The on-call cardiologist receives an alert once these data are obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in turn alerts the paramedic to transport the patient to the destination based on global positioning system (GPS) navigation. A dedicated server will be available round the clock to route all information from one hand held device to the other in ambulance or hospital. Data are simultaneously stored on the server along with the ECG snapshot which can be accessed by teams at the receiving hospital.

Treatment Protocols

There will be two strategies to manage STEMI patients and both are adapted from current American College of Cardiology/American Heart Association and European Society of

Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall, these guidelines intend to minimize the total ischemic time (7).

1. *Primary and Rescue PCI:* All patients with STEMI presenting to a Class A hospital, Class B hospital during working hours, and Class C hospital with an estimated transportation time of less than 60 minutes will undergo primary PCI. The aim is to achieve a door-to-balloon time of less than 90 minutes and a first medical contact to balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed reperfusion (i.e., rescue PCI).
2. *Pharmacoinvasive Strategy:* All patients with STEMI presenting to a Class B hospital outside of working hours or Class D hospital with anticipated long transportation times, unless contraindicated, will receive fibrinolysis as per routine hospital practice with goal of door-to-needle time less than 30 minutes. Patients will then be transferred for an early invasive strategy with coronary angiography and PCI, if indicated, within 3 to 24 hours of receiving fibrinolytic therapy.

All other medical therapy will be at the discretion of the treating physician and the healthcare team. However, the use of immediate dual antiplatelet therapy**, in the form of aspirin and one of the theinopyridine group of drugs such as clopidogrel or prasugrel or ticagrelor** and anticoagulation with heparin or equivalent drugs is encouraged. Other therapies, such as morphine, nitroglycerin, beta-blockers and calcium-channel blockerse, are not standardized.

All participating units will have a single protocol in place for reperfusion therapy and cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on distance, logistics, resources and equipment availability. STEMI kits consisting of

'Operations Manual and Guidelines for Management at First Medical Contact' will be circulated. These operations manual detail the interventional strategy at each point of care: the ambulance, the emergency department, inter-hospital transfer, and the role of the hospitals. A STEMI coordinator responsible for accurate management of the project will be identified at each point of system care.

Patients with chest pain who call '108' will enter the system outside of the hospitals. These patients will be picked up by the EMRI ambulance, will have a preliminary ECG performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist, the ambulance will use GPS to locate the closest hospital in the cluster and re-route the patient there for appropriate treatment. Even before the patient reaches the hospital, the STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital for primary PCI, bypassing a referring hospital even if it is the closest hospital.

Primary and Secondary Outcomes

Our primary outcomes will be based on care provided during the hospitalization and process measures associated with the use of and time to reperfusion therapy. Secondary outcomes will be clinical events that occur during the hospitalization and follow-up, although we recognize that we will be underpowered to detect differences in these events. These are detailed below. **The reference group for comparison of the outcomes in this study will be the pre programme implementation group.**

Primary Outcomes

- Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
- Use of timely reperfusion defined as door-to-balloon time ≤ 90 minutes or door-to-needle ≤ 30 minutes in patients with STEMI treated with primary PCI and fibrinolytic therapy, respectively
- Use of early invasive risk stratification with coronary angiography and PCI in patients treated with fibrinolytic therapy

Secondary Outcomes

- Use of rescue PCI in patients with failed fibrinolysis.
- Composite of the following in-hospital outcomes: mortality, recurrent infarction/ischemia, stroke, major and minor bleeds.
- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

Statistical considerations

Data from all centres will be combined for analysis. Data will be collected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate.

Comparison between patients treated during the enrolment period and post-implementation periods based on the study outcomes will be tested using applicable test of hypothesis such as t-test, chi-square test or non parametric tests.

Eligible patients from the study with reference to the definition of control population and intervention population will be used for statistical comparison. Control population is defined as population included prior to implementation of TN-STEMI programme into a cluster that will provide baseline data for evaluation of operational parameters and outcomes before and after the intervention (i.e., the enrolment period). Intervention population as per protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster into TN-STEMI programme (i.e., the post-implementation period). This will also include patients who were transferred and completed the study protocol, patients who were transferred and did not complete the study prior to intervention and post intervention.

The estimated sample size for the present study that allows for statistical inference for the primary end point uses as reference the Kovai Erode pilot study (4). It is estimated that the study would be adequately powered at 80% with a superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3 clusters. Considering the design of the study (all comers) and the objective of a state-wide program implementation, the enrolment period of 9 months will result in a sample size of 1500 patients. If the sample size cannot be fulfilled during the study time frame, the enrolment period will be extended.

Study oversight, ethical considerations, and data collection and quality

This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the ICMR. Despite the fact that this is a implementation study

focusing on quality improvement, all participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants. The rights, safety and well-being of the study subjects are the most important considerations and should prevail over interests of society and science.

Data collection and quality control:

Data will be collected prospectively from all the participating units from personnel blinded to the aims of the study. Electronic case report forms (eCRFs) must be completed for each patient screened/enrolled and the data for this study will be collected with an electronic data capture application. As required by the ICH GCP (International Conference on Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator will allow direct access to all pertinent medical records in order to allow the verification of data gathered in the eCRFs and for the review of the data collection process. Data will be captured and processed into a quality assured database. The investigator(s)/institution(s) will permit study-related monitoring, audits, and regulatory inspection(s), providing direct access to source data documents. Periodic quality check will be done to ensure proper functioning and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement (QI) reports will be generated for every participating hub hospital to ensure that quality systems are in place. QI will include a review of system administration/ organizational activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will periodically review and evaluate the accumulated study data for participant safety, study conduct, study progress, and make recommendations concerning the continuation, modification, or termination of the project.

Discussion

Reperfusion therapy is critical in the management of patients with STEMI and one of the most powerful predictors of early and late survival; however, its use is considerably hampered by several non-clinical and system-related barriers in low-to-middle income countries like India. Furthermore, primary PCI has increasingly become the preferred method of reperfusion therapy in STEMI management but because of the additional resources that it requires it is frequently unavailable in these settings. Expanding population-wide availability of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects of STEMI systems of care that have been used with great success in Western Europe and North America.

We believe that the TN-STEMI programme will create new opportunities to deliver these therapies in India by addressing various clinical, logistical and societal factors. As in other countries, effective management of STEMI at the community level in India will require executing proven treatment protocols along with efficient and rapid inter hospital transfer within coordinated hospital networks. Regional systems of care such as “Mission: Lifeline” have been successfully used in STEMI management in the US (8). In Europe, ‘hub and spoke’ model of STEMI networks also demonstrate improved adherence to reperfusion therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-For-Life programme of the European Society of Cardiology. Although STEMI management in India may also benefit from such organized systems of care, there are little or no data to support that these approaches improve key processes of care or outcomes in this environment. Hence, understanding the effect of the STEMI network implemented in the state of Tamilnadu will have substantial implications for the country. This approach is particularly worthwhile as it leverages unique public and private partnerships, technological innovation in

monitoring devices, an expanding EMRI ambulance system, and novel strategies for reperfusion therapy and early invasive risk stratification. If successful, this type of network may be extended to the rest of India and even worldwide.

Contributions of authors:

Dr. Thomas Alexander, Dr. Ajit S Mullasari: Conception of trial design and provided the important intellectual content

Dr. Suma M Victor: Drafting of the article

Dr. Ganesh Veerasekar: Drafting of tables and Images

Dr. Kala Subramaniam: Provided the statistical design

Dr. Brahmajee K Nallamothu: Final correction & approval of the version

Disclosures:

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Conflict of interests: The author(s) declare that they have no conflicting interests.

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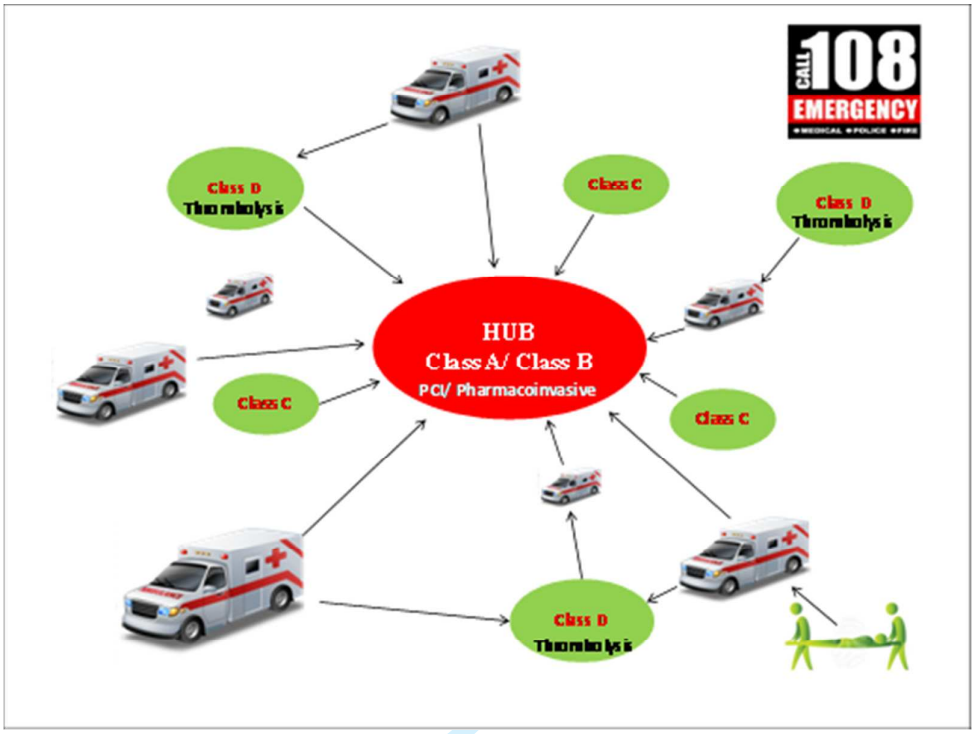

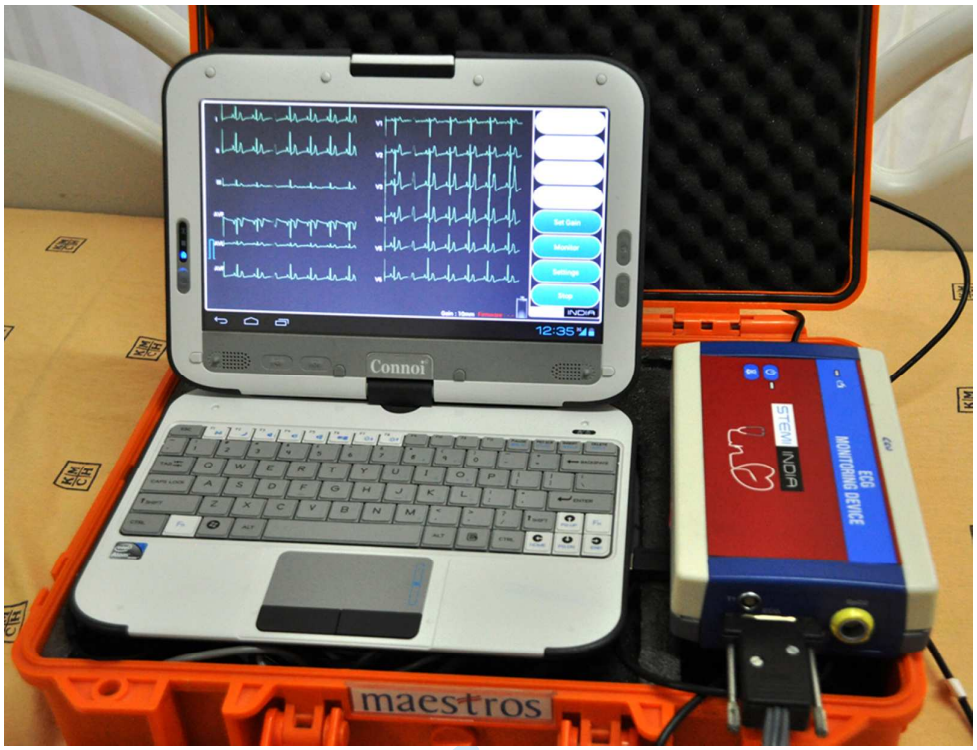

CLUSTER 1:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
CLUSTER 2:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D

	Kanchipuram	
CLUSTER 3:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
CLUSTER 4:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – 'Ice Cream Sandwich' , 2G or 3G connectivity	Android 4.0 –'Ice Cream Sandwich' , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

Table 2: ECG signal specifications:

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

Table 3: Arterial saturation (SaO_2) signal specification:

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO_2 > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

Table 4: Blood pressure (BP) signal specification:

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	 25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.

Table 5: Battery details

Type	Rechargable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

Table 6: Display Device Specifications

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen • 10.1" 1366x768 optional display • Convertible: traditional or touch-optimized tablet mode • Palm-resting feature allows to write and draw comfortably
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN • 3G • GPS
Keyboard/touch Pad	• Water resistant keyboard • Water resistant touch pad (integrated vertical scrolling) • Anti-microbial keyboard
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	• Size including handle: 268mm x (39.5~32mm)

	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

Table 7: Carry case specifications

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS

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Protocol for a prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu - The TN-STEMI Programme

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Protocol for a prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu

The TN-STEMI Programme

Thomas Alexander, Suma M Victor, Ajit S Mullasari, Ganesh Veerasekar, Kala Subramaniam, Brahmajee K Nallamothu

For TN-STEMI Programme Investigators

Abstract

Introduction: Over the last two decades, India has witnessed a staggering increase in the incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher rates of STEMI and younger populations that suffer from it when compared with developed countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary intervention (PCI) are available to only a minority of patients. This gap in care is a result of financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of acute medical services for a majority of its population.

Methods and analysis: This is a prospective, multi-centre, "pre test/post test" Quasi-experimental, community-based study. This programme will use a 'hub-and-spoke' model of an integrated healthcare network based on clusters of primary-care health clinics, small hospitals and large tertiary-care facilities. It is an "all-comers" study which will enrol consecutive patients presenting with STEMI to the participating hospitals. The primary objectives of the study is to improve the use of reperfusion

therapy and reduce the time from first medical contact to device or drug in STEMI patients; and to increase rates of early invasive risk stratification with coronary angiography within3 to 24 hours of fibrinolytic therapy in eligible patients through changes in process of care. Outcomes will be measured with statistical comparison made before and after implementing the TN STEMI programme. The estimated sample size is based on the Kovai Erode Pilot study, which provided initial work on establishing this type of programme in South India. It will be adequately powered at 80% with a superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3 clusters. Thus, the enrolment period of 9 months will result in a sample size of 1500 patients.

Ethics: This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the Indian Council for Medical Research. All participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants.

Dissemination and results: Our findings will be reported through scientific publications, research conferences, and public policy venues aimed at state and local governments in India. If successful this model can be extended to other areas of India as well as serve as a model of STEMI systems of care for low-and-middle income countries across the world.

Registration: Trial is registered with Clinical trial registry of India, No: CTRI/2012/09/003002.

Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays **(3)**. Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach **(3)**. Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it

demonstrated that by linking several smaller, peripheral "spoke" hospitals with a centrally-located, PCI-capable "hub" hospital, the use and timelines of reperfusion therapy could be improved. Encouraged by these results, we now propose a broader 'hub and spoke' model in other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to describe the framework and methods associated with this programme – the first-ever, multi-centre study that aims to improve delivery of reperfusion therapy in India. If successful, this programme can be extended to other areas of the country and serve as a model of STEMI systems of care for low-and-middle income countries.

Methods & Analysis

Study design and objectives

The TN- STEMI programme is a prospective, controlled, multi-centre pre test/post test Quasi- experimental study that has been planned as a community-based treatment programme for improving use and timeliness of reperfusion therapy in patients diagnosed with STEMI as confirmed by an ECG. RCT design was not chosen for this study, primarily because it was not attempting to prove efficacy of a certain treatment or causality assessment. Instead our goal was more focused on implementation of a program that would facilitate quick recognition and shifting of patients for definitive treatment following a standardised pre hospital care in the challenges of India. It involves a stepwise approach that facilitates rapid and definitive restoration of coronary blood flow using a combination of pharmacological and mechanical reperfusion therapies based on the presentation of the patient. This programme will use a 'hub-and-spoke' model that relies on an integrated healthcare network based on clusters of primary-care health clinics and small hospitals built around 4 large tertiary-care facilities that are capable of providing advanced cardiovascular services, including PCI and cardiac surgery. The primary objectives of the

TN-STEMI programme is to use organized systems of care to: (1) improve the use of reperfusion therapy and reduce the time from first medical contact to device or drug in STEMI patients; and (2) increase rates of early invasive risk stratification in eligible patients **by employing a pharmacoinvasive strategy of reperfusion.**

We plan to measure our ability to achieve this overall objective through explicit measurement of changes in processes of care before and after introduction of the TN STEMI programme. Secondary (and implicit) objectives include:

- Integrating care between emergency medical services (EMS) and acute-care clinics and hospitals at the community level in India, especially in rural areas.
- Providing a pragmatic model to understand the challenges associated with developing a national STEMI programme in India.
- To increase public awareness of appropriate STEMI care in India

Study population, facilities and enrolment period

The TN-STEMI programme incorporates an inclusive, "all-comers" study design. Consecutive patients aged 20 years or older with symptoms or signs consistent with acute coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the study, an ECG must have evidence of myocardial injury showing ≥ 1-mm ST-segment elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR), ≥ 1-mm ST-segment elevation in a precordial lead V4 through V6, ≥ 2-mm ST-segment elevation in V1 through V3 or a new left bundle branch block.

Both "hub" hospitals and "spoke" hospitals are included in each of the 4 clusters. The hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke

hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals situated within 30 minutes of a hub hospital have been classified as class C while those beyond 30 minutes were class D hospitals. All participating units had to commit to complying with the study protocol and were required to be within the catchment area for available emergency ambulance services. Details of the hub-and-spoke model are discussed below.

Baseline data on management and outcomes of STEMI patients will be collected for 3 months at all the participating hospitals during an enrolment period that started in the fall of 2012. **This data includes patient's details with address and telephone number, demographic details, personal and medical history in detail such as smoking status whether patient is a current smoker or smoker in the past or non smoker, if a smoker, then the details of quantity of consumption and duration will be collected. Clinical examination findings, investigations, diagnosis, treatment modality, medication details, cardiac catheterization details, outcome will be noted. Baseline data will also include assessment of systems of care- how did the patient come to the hospital, total ischemic time, the mode of treatment, transport, time intervals of onset of chest pain, time reached the hospital, time taken to perform ECG, time of starting of treatment etc.** The enrolment period will be "rolling" for each of the hospitals and followed by 9 months of post-implementation data collection on STEMI patients after execution of the TN-STEMI programme. Outcomes that we will be evaluating are discussed in detail below and include data on processes of care that will be available during the hospitalization and follow up data for one year from the index event; the 1 year follow up will either be a hospital visit, if it is the routine practice at the local site or a telephonic follow up if hospital visit is not required by the treating hospital. Estimated loss to follow up is 20%. **This estimate is based on our experiences with clinical research in these communities and is conservative.**

TN-STEMI programme: the hub and spoke model

We have organized the network of hospitals within the TN-STEMI programme using a "hub-and-spoke" model that recognizes four classes of healthcare facilities that care for STEMI patients in India:

- **Class A Hospital -** Class A hospitals are PCI-capable hospitals with healthcare teams available 24/7 for managing STEMI and its complications. Patients admitted to these hospitals typically undergo primary PCI with an aim of door-to-balloon time less than 90 minutes.
- **Class B Hospital -** These are PCI-capable hospitals, but primary PCI cannot be performed outside of working hours. Patients admitted to a class B hospital outside of working hours are typically are treated with fibrinolysis with a goal of door-to-needle time less than 30 minutes. Patients would be taken for catheterization within the next 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives during working hours.
- **Class C Hospital –** These are healthcare facilities and hospital with the capability to perform and transmit ECGs *and* that are located within 30 minutes of a Class A or Class B hospital. **These hospitals do not have fibrinolysis capability**. All Class C hospitals would constitute the spokes of the Class A/B hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital, **depending on the availability primary PCI.** This process of transfer should ideally take less than 60 minutes.
- **Class D Hospital -** This class of healthcare facilities and hospitals have the capability to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable hospital. All of these are capable of providing fibrinolysis. All Class D hospitals

would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D hospital are treated with fibrinolysis after confirmation of STEMI as per routine hospital practice. After informing the receiving hospital that is linked to it, transfer of the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated PCI, within the next 3 to 24 hours.

Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D hospitals. A full list of the participating hospitals organized by their classes is presented in Table 1. Figure 1 shows the "hub-and-spoke" model; Figure 2 shows a geographical map of Tamilnadu State showing locations of clusters of "hub-and-spoke" hospitals in the TN-STEMI programme.

Key partners in TN-STEMI programme

The TN-STEMI programme involves 3 key partners from both the public and private sectors:

1. **Government of Tamilnadu – Chief Minister's Health Insurance Scheme.** A recent and important development that is relevant to the TN-STEMI programme in India has been the establishment and growth of government-sponsored social insurance coverage for healthcare among those below the poverty line. This has been a state-based development, including the Chief Minister's Health Insurance Scheme in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this programme. This requirement will ensure that patients from all social classes can receive timely and suitable treatment for STEMI with no out-of-pocket expenses incurred for their hospitalization. The Chief Minister's Health Insurance scheme is currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari TTK Healthcare, MediAssist and MD India Third Party Administrator.

2. **EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and Research Institute (GVK-EMRI) operates as a public-private-partnership and is recognized as a not-for-profit entity. It is an organization that has pioneered the development of emergency medical services (EMS) in India, including training paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI ambulance services may be activated by a patient with chest pain or a healthcare facility using the" Call 108" system. Units within this EMS are capable of acquiring ECGs, transmitting ECGs to an 'on call cardiologist' for STEMI confirmation, locating the nearest PCI-capable hospital using GPS provided by a coordinating centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances will also transport patients from the spoke hospital to the hub hospitals after initial evaluation and possible treatment**.**

3. **STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in India led by physicians from across the country. The purpose of this organization is to review and disseminate the latest information from across the world on STEMI management to providers involved in STEMI care in India; to help organize and train STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the context of healthcare systems' needs and resources in India. Other goals include: facilitating and contributing to national STEMI guidelines within India and improving public education to reduce delays in accessing care. The organization's role in the TN-STEMI programme has been to provide expertise in the development and oversight of the study protocol to meet standards of care within India for STEMI patients.

In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and Maestro technologies, to coordinate the development of novel software and hardware

(described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved with the clinical administration of the trial. The TN-STEMI programme is supported by an independent grant from the Indian Council for Medical Research (ICMR).

STEMI Technology

A novel aspect of the TN-STEMI programme is the implementation of new hardware and software components to optimize the performance and transmission of ECGs and other clinical information across the network of hospitals in India by paramedics, nurses and physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:

1. ***ECG recording device*** - ECG devices will record the patient's ECG which would then be transmitted by paramedics to a hand held device of the STEMI coordinator in a hub hospital.
2. ***Vital signs monitoring device*** - This device will record the patient's vital signs and hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure, heart rate and rhythm strip. This will also permit the transmission of key information by paramedics to STEMI coordinators at hub hospitals.
3. ***Display and transmitting device*** - Each STEMI coordinator will have a hand held device which collects and transmits data when required with sufficient battery support. This will allow for communication between STEMI coordinators and on-call cardiologists at the Class A/B hospitals.

Coordination of the hardware units by paramedics, STEMI coordinators and on-call cardiologists will be performed through unique software applications that are specifically designed for the TN-STEMI programme to be used across a universal platform for multiple devices. These are summarized in the Appendix.

The paramedic and STEMI coordinators will capture the patient demographic details along with a checklist for eligibility for fibronolytic therapy. This information along with the

ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and decide on initial treatment. The on-call cardiologist receives an alert once these data are obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in turn alerts the paramedic to transport the patient to the destination based on global positioning system (GPS) navigation. A dedicated server will be available round the clock to route all information from one hand held device to the other in ambulance or hospital. Data are simultaneously stored on the server along with the ECG snapshot which can be accessed by teams at the receiving hospital.

Treatment Protocols

There will be two strategies to manage STEMI patients and both are adapted from current American College of Cardiology/American Heart Association and European Society of Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall, these guidelines intend to minimize the total ischemic time (7).

1. *Primary and Rescue PCI:* All patients with STEMI presenting to a Class A hospital, Class B hospital during working hours, and Class C hospital with an estimated transportation time of less than 60 minutes will undergo primary PCI. The aim is to achieve a door-to-balloon time of less than 90 minutes and a first medical contact to balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed reperfusion (i.e., rescue PCI).
2. *Pharmacoinvasive Strategy:* All patients with STEMI presenting to a Class B hospital outside of working hours or Class D hospital with anticipated long transportation times, unless contraindicated, will receive fibrinolysis as per routine hospital practice

with goal of door-to-needle time less than 30 minutes. Patients will then be transferred for an early invasive strategy with coronary angiography and PCI, if indicated, within 3 to 24 hours of receiving fibrinolytic therapy.

All other medical therapy will be at the discretion of the treating physician and the healthcare team. However, the use of immediate dual antiplatelet therapy**, in the form of aspirin and one of the theinopyridine group of drugs such as clopidogrel or prasugrel or ticagrelor** and anticoagulation with heparin or equivalent drugs is encouraged. Other therapies, such as morphine, nitroglycerin, beta-blockers and calcium-channel blockerse, are not standardized.

All participating units will have a single protocol in place for reperfusion therapy and cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on distance, logistics, resources and equipment availability. STEMI kits consisting of 'Operations Manual and Guidelines for Management at First Medical Contact' will be circulated. These operations manual detail the interventional strategy at each point of care: the ambulance, the emergency department, inter-hospital transfer, and the role of the hospitals. A STEMI coordinator responsible for accurate management of the project will be identified at each point of system care.

Patients with chest pain who call '108' will enter the system outside of the hospitals. These patients will be picked up by the EMRI ambulance, will have a preliminary ECG performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist, the ambulance will use GPS to locate the closest hospital in the cluster and re-route the patient there for appropriate treatment. Even before the patient reaches the hospital, the STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on

the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital for primary PCI, bypassing a referring hospital even if it is the closest hospital.

Primary and Secondary Outcomes

Our primary outcomes will be based on care provided during the hospitalization and process measures associated with the use of and time to reperfusion therapy. Secondary outcomes will be clinical events that occur during the hospitalization and follow-up, although we recognize that we will be underpowered to detect differences in these events. These are detailed below. **The reference group for comparison of the outcomes in this study will be the pre programme implementation group.**

Primary Outcomes

- Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
- Use of timely reperfusion defined as door-to-balloon time ≤ 90 minutes or door-to-needle ≤ 30 minutes in patients with STEMI treated with primary PCI and fibrinolytic therapy, respectively
- Use of early invasive risk stratification with coronary angiography and PCI in patients treated with fibrinolytic therapy

Secondary Outcomes

- Use of rescue PCI in patients with failed fibrinolysis.
- Composite of the following in-hospital outcomes: mortality, recurrent infarction/ischemia, stroke, major and minor bleeds.

- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

Statistical considerations

Data from all centres will be combined for analysis. Data will be **c**ollected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate. Comparison between patients treated during the enrolment period and post-implementation periods based on the study outcomes will be tested using applicable test of hypothesis such as t-test, chi-square test or non parametric tests.

Eligible patients from the study with reference to the definition of control population and intervention population will be used for statistical comparison. Control population is defined as population included prior to implementation of TN-STEMI programme into a cluster that will provide baseline data for evaluation of operational parameters and outcomes before and after the intervention (i.e., the enrolment period). Intervention population as per protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster into TN-STEMI programme (i.e., the post-implementation period). This will also include patients who were transferred and completed the study protocol, patients who were transferred and did not complete the study prior to intervention and post intervention.

The estimated sample size for the present study that allows for statistical inference for the primary end point uses as reference the Kovai Erode pilot study (4). It is estimated that the study would be adequately powered at 80% with a superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3 clusters. Considering the design of the study (all comers) and the objective of a state-wide program implementation, the enrolment period of 9 months will result in a sample size of 1500 patients. If the sample size cannot be fulfilled during the study time frame, the enrolment period will be extended.

Study oversight, ethical considerations, and data collection and quality

This study will be conducted in accordance with the ethical principles that have their origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research on human participants' as laid down by the ICMR. Despite the fact that this is a implementation study focusing on quality improvement, all participating hospitals will still obtain local ethics committee approval of the study protocol and written informed consent will be obtained from all participants. The rights, safety and well-being of the study subjects are the most important considerations and should prevail over interests of society and science.

Data collection and quality control:

Data will be collected prospectively from all the participating units from personnel blinded to the aims of the study. Electronic case report forms (eCRFs) must be completed for each patient screened/enrolled and the data for this study will be collected with an electronic data capture application. As required by the ICH GCP (International Conference on Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator will allow direct access to all pertinent medical records in order to allow the verification of data gathered in the eCRFs and for the review of the data collection process. Data will be

captured and processed into a quality assured database. The investigator(s)/institution(s) will permit study-related monitoring, audits, and regulatory inspection(s), providing direct access to source data documents. Periodic quality check will be done to ensure proper functioning and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement (QI) reports will be generated for every participating hub hospital to ensure that quality systems are in place. QI will include a review of system administration/ organizational activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will periodically review and evaluate the accumulated study data for participant safety, study conduct, study progress, and make recommendations concerning the continuation, modification, or termination of the project.

Discussion

Reperfusion therapy is critical in the management of patients with STEMI and one of the most powerful predictors of early and late survival; however, its use is considerably hampered by several non-clinical and system-related barriers in low-to-middle income countries like India. Furthermore, primary PCI has increasingly become the preferred method of reperfusion therapy in STEMI management but because of the additional resources that it requires it is frequently unavailable in these settings. Expanding population-wide availability of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects of STEMI systems of care that have been used with great success in Western Europe and North America.

We believe that the TN-STEMI programme will create new opportunities to deliver these therapies in India by addressing various clinical, logistical and societal factors. As in

other countries, effective management of STEMI at the community level in India will require executing proven treatment protocols along with efficient and rapid inter hospital transfer within coordinated hospital networks. Regional systems of care such as “Mission: Lifeline” have been successfully used in STEMI management in the US (8). In Europe, ‘hub and spoke’ model of STEMI networks also demonstrate improved adherence to reperfusion therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-For-Life programme of the European Society of Cardiology. Although STEMI management in India may also benefit from such organized systems of care, there are little or no data to support that these approaches improve key processes of care or outcomes in this environment. Hence, understanding the effect of the STEMI network implemented in the state of Tamilnadu will have substantial implications for the country. This approach is particularly worthwhile as it leverages unique public and private partnerships, technological innovation in monitoring devices, an expanding EMRI ambulance system, and novel strategies for reperfusion therapy and early invasive risk stratification. If successful, this type of network may be extended to the rest of India and even worldwide.

Contributions of authors:

Dr. Thomas Alexander, Dr. Ajit S Mullasari: Conception of trial design and provided the important intellectual content

Dr. Suma M Victor: Drafting of the article

Dr. Ganesh Veerasekar: Drafting of tables and Images

Dr. Kala Subramaniam: Provided the statistical design

Dr. Brahmajee K Nallamothu: Final correction & approval of the version

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Conflict of interests: The author(s) declare that they have no conflicting interests.

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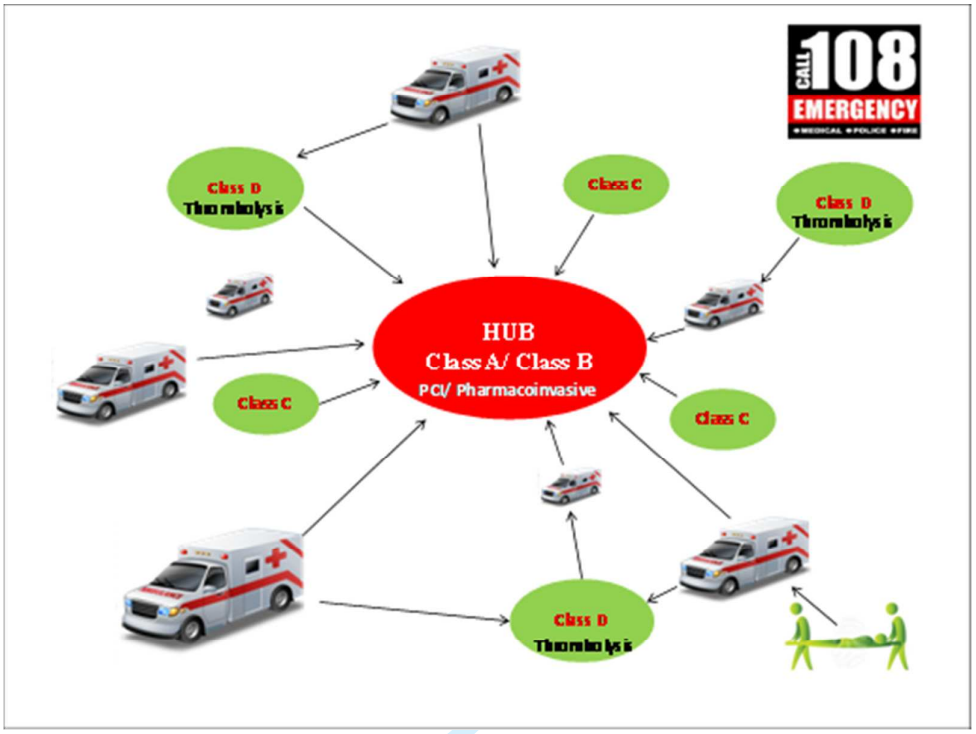

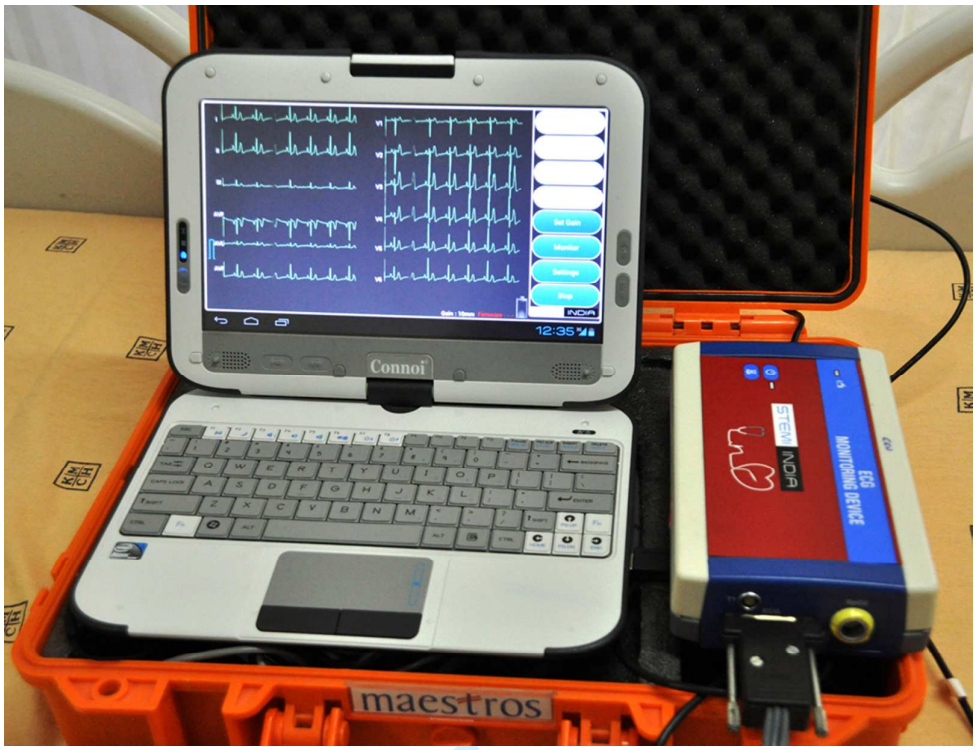

CLUSTER 1:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
CLUSTER 2:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D

	Kanchipuram	
CLUSTER 3:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
CLUSTER 4:		
HUB HOSPITAL	**SPOKE HOSPITAL**	**CLASS**
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – 'Ice Cream Sandwich' , 2G or 3G connectivity	Android 4.0 –'Ice Cream Sandwich' , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

Table 2: ECG signal specifications:

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

Table 3: Arterial saturation (SaO_2) signal specification:

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO_2 > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

Table 4: Blood pressure (BP) signal specification:

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	 25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.

Table 5: Battery details

Type	Rechargable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

Table 6: Display Device Specifications

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen • 10.1" 1366x768 optional display • Convertible: traditional or touch-optimized tablet mode • Palm-resting feature allows to write and draw comfortably
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN • 3G • GPS
Keyboard/touch Pad	• Water resistant keyboard • Water resistant touch pad (integrated vertical scrolling) • Anti-microbial keyboard
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	• Size including handle: 268mm x (39.5~32mm)

	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

Table 7: Carry case specifications

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS

Protocol No: LA-RSH/103/2012	Site ID: ☐☐-☐☐-☐ Patient ID:_____

Case Report Form (Baseline Data Collection)
Class A/B Hospital

A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.

Protocol No : LA-RSH/103/2012	**Protocol Version & Date : Version 2.0, 18-Apr-2012**
CRF (Baseline Data Collection) : Version 1.0	**Sponsor : STEMI India Group**

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		**Alternate Contact Details**	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/_____/_____ DD MMM YYYY	Age:_____years	Gender : 1☐ Male 2☐ Female
Occupation:_____	Tobacco Smoking Status	1☐ Non Smoker 2☐ Current Smoker 3☐ Past Smoker 4☐ Smoking Status Unknown 5☐ Passive 99☐ Others, please specify _____
If smoking, please provide the details:		
Number:_____	Duration:_____	Type:_____

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Clinical examination		
Height: _____ cm	Weight: _____ kg	BMI : _____Kg/m^2
Blood Pressure:_____/_____ mm of Hg Systolic Diastolic	Heart Rate : _____ Beats/min	

Diagnosis	
Presenting complaints:	1☐ Chest pain 2☐ Palpitations 3☐ Pain in other locations (Arm pain, Jaw Pain…….) 4☐Diaphoresis 5☐Syncope 6☐ Dyspnea 99☐ Others, specify_____

DIRECT ADMISSION	☐ Not Applicable		
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:____ HH MM	☐ NA
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance 9☐ Not Applicable		
If Ambulance, Please provide the below details:			
Ambulance call time: ____:____ HH MM	Ambulance arrival time: ____:____ HH MM	☐ NA	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:____ HH MM	☐ NA
Initial ECG Time:	____:____ HH MM	☐ NA	
Time of STEMI confirmation:	____:____ HH MM	☐ NA	
Location of infarction (as per ECG)			

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DIRECT EMRI TRANSFER	☐ Not Applicable		
Date and Time of Call to EMRI	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of EMRI despatch	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Time of arrival at patient site:	____:_____ HH MM	☐ NA	
Time of departure from scene:	____:_____ HH MM	☐ NA	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Location of ECG Recording:	3☐ Ambulance 1☐ Hospital 9☐ Not Applicable		
Initial ECG Time:	____:_____ HH MM	☐ NA	
Time of STEMI confirmation:	____:_____ HH MM	☐ NA	
Location of infarction(as per ECG)			

EMRI TRANSFER FROM C/D SPOKE		
Mention the spoke hospital patient has been transferred from:	3☐ Class C 4☐ Class D	
Is the patient accompanied with the Baseline CRF from the spoke hospital:	1☐ Yes 0☐ No	
If yes, has the form been attached to the Class A/B CRF:	1☐ Yes 0☐ No	
Time of arrival in Hospital A/B:	____:_____ HH MM	☐ NA

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NON STEMI CLUSTER ENTRY	☐ Not Applicable		
Time of arrival of patient at non STEMI cluster Hospital:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Initial ECG Time:	____:_____ HH MM	☐ NA	
Time of STEMI confirmation:	____:_____ HH MM	☐ NA	
Location of infarction (as per ECG)			
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance 4☐ EMRI 5☐ Not known		
EMRI/Ambulance call time: ____:_____ HH MM	EMRI/Ambulance arrival time: ____:_____ HH MM	☐ NA	
Time of start of patient transfer:	____:_____ HH MM	☐ NA	
Time of arrival in Hospital A/B:	____:_____ HH MM	☐ NA	

Medication at Previous Hospital/ during Transfer				
Was any medication administered to the patient at previous hospital/during transfer?	1☐ Yes 0☐ No			
If Yes, please provide the below details:				
Medication	**Route**	**Dose**	**Date of Administration (DD/MMM/YYYY)**	**Time of Administration (HH:MM)**

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Patient ID:_____

Fibrinolytic Checklist			
Sl.No		**Responses**	
1.	Is Systolic BP greater than 180 mm Hg ?	1☐ Yes	0☐ No
2.	Is Diastolic BP greater than 110 mm Hg?	1☐ Yes	0☐ No
3.	Is Right vs. left arm systolic BP difference greater than 15 mm Hg ?	1☐ Yes	0☐ No
4.	History of structural central nervous system disease ?	1☐ Yes	0☐ No
5.	Significant closed head/facial trauma within the previous 3 months ?	1☐ Yes	0☐ No
6.	Recent (within 6 wks) major trauma, surgery (including laser eye surgery) GI/GU bleed ?	1☐ Yes	0☐ No
7.	Bleeding or clotting problem or on blood thinners?	1☐ Yes	0☐ No
8.	CPR greater than 10 minutes?	1☐ Yes	0☐ No
9.	Pregnant Female?	1☐ Yes	0☐ No
10.	Serious systemic disease (eg. advanced / terminal cancer, severe liver or kidney disease) ?	1☐ Yes	0☐ No
11.	Does the patient have severe heart failure or cardiogenic shock such that PCI is preferable?	1☐ Yes	0☐ No
12.	Pulmonary edema (rales greater than halfway up)	1☐ Yes	0☐ No
13.	Systemic hypoperfusion (cool, clammy)	1☐ Yes	0☐ No

Medication Prior to Thrombolysis					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____					

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Patient ID:_____

Thrombolysis							
Was the subject Thrombolysed:	1☐ Yes 0☐ No 9☐ Not Applicable						
If Yes, Please provide the below details:							
Thrombolytic Agent	Route of Administration	Actual Dosage Administered		Start of Thrombolysis		Completion of Thrombolysis	
		Mg	U	DD/MMM/YYY	HH : MM	DD/MMM/YYY	HH : MM
☐ Streptokinase							
☐ Tenectaplase							
☐Others, Specify _____							
90-120 min ECG Time:	____:____ HH MM			☐ NA			

Medication Prior to PCI					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Prasugrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____ _					

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Patient ID:_____

PCI					
Cath Lab activation time:	_____:_____ HH MM			☐ NA	
Patient Arrival Time at Cath Lab	_____:_____ HH MM			☐ NA	
Date and Time of Vascular Access:	_____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Date and Time of Start of Diagnostic Angiography:	_____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Date and Time of End of Diagnostic Angiography:	_____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Catheter Access:	1☐Radial			2☐Femoral	
Findings of Diagnostic Angiography:	1☐ Single Vessel Disease			2☐ Double Vessel	
	3☐ Triple Vessel Disease			4☐ Insignificant Disease	
Aspiration	1☐ Yes 0☐ No				
Date and Time of Balloon Inflation/Stent deployment:	_____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Vessels	**Stenosis?**	**Severity**	**Culprit Vessel**	**No. of Stents**	**Type of Stent**
☐ Left Anterior Descending (LAD)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Left Circumflex Artery (LCX)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Right Coronary Artery (RCA)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Others, Specify _____	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd

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Patient ID:_____

Medication in Cath Lab					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Prasugrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____ _					
GP IIb/IIIa Inhibitors ☐Abciximab ☐Eptifibatide ☐Tirofiban ☐Others Specify:_____					
☐Bivaluridin					
☐Fondoparinaux					

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Patient ID:_____

Other Medication During Hospitalization	
Was any other medication administered to the patient during hospitalization in Hospital A/B?	1☐ Yes 0☐ No
If Yes, please provide the below details:	

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Discharge Summary	
Date of Discharge:	____/_____/_____ DD MMM YYYY
Recommendations:	1☐ Conservative Treatment 2☐ Referred to Class A/B hospital 3☐ Non STEMI Cluster hospital 99☐Others, Specify_____

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Patient ID:_____

Medication on Discharge	
Was the Patient prescribed any medication on discharge? If Yes, provide the details below:	1☐ Yes 0☐ No

Sl No.	Medication Name

Adverse Events	
Adverse event experienced?:	1☐ Yes 0☐ No
If Yes, provide the below details:	

Sl #	Adverse Event	Response	Comments
1	Stroke	1☐ Yes 0☐ No	
2	Cardiogenic Shock	1☐ Yes 0☐ No	
3	Access site Hemorrhage	1☐ Yes 0☐ No	
4	Major Bleed#	1☐ Yes 0☐ No	
5	Minor Bleed#	1☐ Yes 0☐ No	
6	Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
7	SymptomaticIschemia	1☐ Yes 0☐ No	
8	Others Specify_____	1☐ Yes 0☐ No	

#Derived based on TIMI Score Scale

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Patient ID:_____

ADDITIONAL INFORMATION

Medical/Surgical History

Does the subject have any other clinically significant medical /surgical history?
If Yes, provide the details below: 1☐ Yes 0☐ No

Symptom/Diagnosis/ Procedure[#]	Response	Medication (If Applicable)
Diabetes Mellitus	1☐ Yes 0☐ No	
Hypertension	1☐ Yes 0☐ No	
Peripheral Vascular Disease	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Dyslipidemia	1☐ Yes 0☐ No	
Allergies	1☐ Yes 0☐ No	
Bronchial Asthma	1☐ Yes 0☐ No	
CAD (including Angina and MI)	1☐ Yes 0☐ No	
Others, Specify_____	1☐ Yes 0☐ No	
_____		

If the response to Medical History is checked as CAD, please provide previous management details:

Previous Management	Date	Details
☐ Medical Management	___ / _____ / _____ DD MMM YYYY	
☐ PCI	___ / _____ / _____ DD MMM YYYY	
☐ CABG	___ / _____ / _____ DD MMM YYYY	
☐ Others Specify: _____	___ / _____ / _____ DD MMM YYYY	

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Patient ID:_____

Investigator Comments (if any)

_____

_____

Investigator Declaration

I cetify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.

Investigator Name : _____

Investigator Signature : _____ ____/_____/_____
DD MMM YYYY

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Patient ID:_____

Follow up (1 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Protocol No: LA-RSH/103/2012

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Patient ID:_____

Follow up (6 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | |

Patient ID:_____

Follow up (1 Year)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Protocol No: LA-RSH/103/2012	Site ID: __ __ - __ __ - C Patient ID:_____

Case Report Form (Baseline Data Collection)
Class C Hospital –Direct Admission

A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.

Protocol No : LA-RSH/103/2012	**Protocol Version & Date : Version 2.0, 18-Apr-2012**
CRF (Baseline Data Collection) : Version 1.0	**Sponsor : STEMI India Group**

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		**Alternate Contact Details**	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/_____/_____ DD MMM YYYY	Age:_____years	Gender : 1☐ Male 2☐ Female
Occupation:_____	Tobacco Smoking Status	1☐ Non Smoker 2☐ Current Smoker 3☐ Past Smoker 4☐ Smoking Status Unknown 5☐ Passive 99☐ Others, please specify _____
If smoking, please provide the details:		
Number:_____	Duration:_____	Type:_____

Protocol No: LA-RSH/103/2012	Site ID: __ __ - __ __ - C Patient ID:_____

Clinical examination		
Height: _____ cm	Weight: _____ kg	BMI : _____Kg/m^2
Blood Pressure:_____/_____ mm of Hg Systolic Diastolic	Heart Rate : _____ Beats/min	

Diagnosis		
Presenting complaints:	1☐ Chest pain 2☐ Palpitations 3☐ Pain in other locations (Arm pain, Jaw Pain…….) 4☐ Diaphoresis 5☐ Syncope 6☐ Dyspnea 99☐ Others, specify_____	
Date and Time of Arrival at Hospital	____/____/_____ DD MMM YYYY	____:_____ HH MM
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance	
If Ambulance, Please provide the below details:		
Ambulance call time: ____:_____ HH MM	Ambulance arrival time: ____:_____ HH MM	
Date and Time of Onset of Symptom:	____/_____/_____ DD MMM YYYY	____:_____ HH MM
Date and Time of FMC:	____/_____/_____ DD MMM YYYY	____:_____ HH MM
Initia ECG Time:	____:_____ HH MM	
Time of STEMI confirmation:	____:_____ HH MM	
Location of infarction(as per ECG)		

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Patient ID:_____

Medication During Hospitalization		
Was any other medication administered to the patient during hospitalization?	1☐ Yes	0☐ No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Discharge Summary	
Date of Discharge:	____/_____/_____ DD MMM YYYY
Recommendations:	1☐ Conservative Treatment 2☐ Referred to Class A/B hospital 3☐ Non STEMI Cluster hospital 99☐Others, Specify_____

Medication on Discharge		
Was the Patient prescribed any medication on discharge? If Yes, provide the details below:	1☐ Yes	0☐ No

Sl No.	Medication Name

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Referral Hospital			
Type of Referral hospital notified:	1☐ Class A	2☐ Class B	99☐ Others,Specify_____ _____
Details of Referral Hospital:	Name: Address:		
Date and Time of notification to Referral Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	
Mode of Transportaion to Referral Hospital:	1☐ Private	3☐ Ambulance	4☐ EMRI
If EMRI or Ambulance, provide the below details:			
Call Time:	____:_____ HH MM		
Arrival Time:	____:_____ HH MM		
Transport Start Time:	____:_____ HH MM		
Management at Referral Hospital			
1☐ PCI			
2☐ Medical Management			
3☐ Unknown			
99☐ Others, Specify_____			

Protocol No: LA-RSH/103/2012

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Patient ID:_____

Adverse Events			
Adverse event experienced?:	1☐ Yes 0☐ No		
If Yes, provide the below details:			
Sl #	**Adverse Event**	**Response**	**Comments**
1	Stroke	1☐ Yes 0☐ No	
2	Cardiogenic Shock	1☐ Yes 0☐ No	
3	Access site Hemorrhage	1☐ Yes 0☐ No	
4	Major Bleed#	1☐ Yes 0☐ No	
5	Minor Bleed#	1☐ Yes 0☐ No	
6	Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
7	SymptomaticIschemia	1☐ Yes 0☐ No	
8	Others Specify_____	1☐ Yes 0☐ No	

#derived based on TIMI Score Scale

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | C |

Patient ID:_____

ADDITIONAL INFORMATION		
Medical/Surgical History		
Does the subject have any other clinically significant medical /surgical history? If Yes, provide the details below:	1☐ Yes 0☐ No	
Symptom/Diagnosis/ Procedure#	**Response**	**Medication (If Applicable)**
Diabetes Mellitus	1☐ Yes 0☐ No	
Hypertension	1☐ Yes 0☐ No	
Peripheral Vascular Disease	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Dyslipidemia	1☐ Yes 0☐ No	
Allergies	1☐ Yes 0☐ No	
Bronchial Asthma	1☐ Yes 0☐ No	
CAD (including Angina and MI)	1☐ Yes 0☐ No	
Others, Specify_____	1☐ Yes 0☐ No	
_____		

If the response to Medical History is checked as CAD, please provide previous management details:		
Previous Management	**Date**	**Details**
☐ Medical Management	___ / _____ / _____ DD MMM YYYY	
☐ PCI	___ / _____ / _____ DD MMM YYYY	
☐ CABG	___ / _____ / _____ DD MMM YYYY	
☐ Others Specify: _____	___ / _____ / _____ DD MMM YYYY	

Protocol No: LA-RSH/103/2012	Site ID: __ __ - __ __ - C
	Patient ID:_____

Investigator Comments

_____

_____

Investigator Declaration

I cetify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.

Investigator Name : _____

Investigator Signature : _____ ____/_____/_____
DD MMM YYYY

Protocol No: LA-RSH/103/2012	Site ID: | | - | | | - | D | Patient ID:_____

Case Report Form (Baseline Data Collection)
Class D Hospital –Direct Admission/EMRI Transfer

A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.

Protocol No : LA-RSH/103/2012	**Protocol Version & Date : Version 2.0, 18-Apr-2012**
CRF (Baseline Data Collection) : Version 1.0	**Sponsor : STEMI India Group**

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		**Alternate Contact Details**	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/_____/_____ DD MMM YYYY	Age:_____years	Gender : 1☐ Male 2☐ Female
Occupation:_____	Tobacco Smoking Status	1☐ Non Smoker 2☐ Current Smoker 3☐ Past Smoker 4☐ Smoking Status Unknown 5☐ Passive 99☐ Others, please specify _____
If smoking, please provide the details:		
Number:_____	Duration:_____	Type:_____

Protocol No: LA-RSH/103/2012	Site ID: ☐☐-☐☐-D Patient ID:_____

Clinical examination		
Height: _____ cm	Weight: _____ kg	BMI : _____Kg/m^2
Blood Pressure:_____/_____ mm of Hg Systolic Diastolic	Heart Rate : _____ Beats/min	

Patient admission to hospital:	1☐Direct Admission 2☐Direct EMRI Transfer 3☐ Referring Hospital/Clinic

If the Patient admission was through Direct EMRI Transfer, please fill the below details:

EMRI			
Date and Time of Call to EMRI	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Date and Time of EMRI despatch	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Time of Arrival at Patient site:	____:_____ HH MM	☐ Not available	
Time of departure from scene:	____:_____ HH MM	☐ Not available	

Diagnosis			
Presenting complaints:	1☐ Chest pain 2☐ Palpitations 3☐ Pain in other locations (Arm pain, Jaw Pain…….)	4☐Diaphoresis 5☐Syncope 6☐ Dyspnea 99☐ Others, specify_____	
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance 9☐ Not Applicable		
If Ambulance, Please provide the below details:			
Ambulance call time: ____:_____ HH MM	Ambulance arrival time: ____:_____ HH MM	☐ Not available	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Location of ECG Recording:	3☐ Ambulance 1☐ Hospital 2☐ Referring Hospital/Clinic 9☐ Not Applicable		
Initial ECG Time:	____:_____ HH MM	☐ Not available	
Time of STEMI confirmation:	____:_____ HH MM	☐ Not available	
Location of infarction (as per ECG)			

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Medication at Previous Hospital/ During Transfer	
Was any medication administered to the patient at previous hospital/during transfer?	1☐ Yes 0☐ No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Fibrinolytic Checklist			
Sl.No		Responses	
1.	Is Systolic BP greater than 180 mm Hg ?	1☐ Yes	0☐ No
2.	Is Diastolic BP greater than 110 mm Hg?	1☐ Yes	0☐ No
3.	Is Right vs. left arm systolic BP difference greater than 15 mm Hg ?	1☐ Yes	0☐ No
4.	History of structural central nervous system disease ?	1☐ Yes	0☐ No
5.	Significant closed head/facial trauma within the previous 3 months ?	1☐ Yes	0☐ No
6.	Recent (within 6 wks) major trauma, surgery (including laser eye surgery) GI/GU bleed ?	1☐ Yes	0☐ No
7.	Bleeding or clotting problem or on blood thinners?	1☐ Yes	0☐ No
8.	CPR greater than 10 minutes?	1☐ Yes	0☐ No
9.	Pregnant Female?	1☐ Yes	0☐ No
10.	Serious systemic disease (eg. advanced / terminal cancer, severe liver or kidney disease) ?	1☐ Yes	0☐ No
11.	Does the patient have severe heart failure or cardiogenic shock such that PCI is preferable?	1☐ Yes	0☐ No
12.	Pulmonary edema (rales greater than halfway up)	1☐ Yes	0☐ No
13.	Systemic hypoperfusion (cool, clammy)	1☐ Yes	0☐ No

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Patient ID:_____

Medication Prior to Thrombolysis					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____					

Thrombolysis							
Was the subject Thrombolysed:	1☐ Yes 0☐ No						
If Yes, Please provide the below details:							
Thrombolytic Agent	Route of Administration	Actual Dosage Administered		Start of Thrombolysis		Completion of Thrombolysis	
		Mg	U	DD/MMM/YYY	HH : MM	DD/MMM/YYY	HH : MM
☐ Streptokinase							
☐ Tenectaplase							
☐Others, Specify _____							
90-120 min ECG Time:	____:____ HH MM			☐ NA			

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Site ID: | | | - | | | - | D |

Patient ID:_____

Other Medication During Hospitalization	
Was any other medication administered to the patient during hospitalization?	1☐ Yes 0☐ No
If Yes, please provide the below details:	

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Discharge Summary	
Date of Discharge:	____/_____/_____ DD MMM YYYY
Recommendations:	1☐ Conservative Treatment 2☐ Referred to Class A/B hospital 3☐ Non STEMI Cluster hospital 99☐ Others, Specify_____

Protocol No: LA-RSH/103/2012

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Patient ID:_____

Medication on Discharge	
Was the Patient prescribed any medication on discharge? If Yes, provide the details below:	1☐ Yes 0☐ No

Sl No.	Medication Name

Adverse Events			
Adverse event experienced?:	1☐ Yes 0☐ No		
If Yes, provide the below details:			
Sl #	**Adverse Event**	**Response**	**Comments**
1	Stroke	1☐ Yes 0☐ No	
2	Cardiogenic Shock	1☐ Yes 0☐ No	
3	Access site Hemorrhage	1☐ Yes 0☐ No	
4	Major Bleed#	1☐ Yes 0☐ No	
5	Minor Bleed#	1☐ Yes 0☐ No	
6	Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
7	SymptomaticIschemia	1☐ Yes 0☐ No	
8	Others Specify_____	1☐ Yes 0☐ No	

#Derived based on TIMI Score Scale

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Referral Hospital				
Type of hospital referred :	1☐ STEMI Cluster hospital	2☐ Non STEMI Cluster hospital		
If STEMI Cluster please specify:	1☐ Class A	2☐ Class B		
Details of Referral Hospital:	Name: Address:			
Date and Time of notification to Referral Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available	
Mode of Transportaion to Referral Hospital:	1☐ Private	3☐ Ambulance	4☐ EMRI	5☐ Not known
If EMRI or Ambulance, provide the below details:				
Call Time:	____:_____ HH MM	☐ Not available		
Arrival Time:	____:_____ HH MM	☐ Not available		
Transport Start Time:	____:_____ HH MM	☐ Not available		
Management at Referral Hospital				
1☐ PCI				
2☐ Medical Management				
3☐ Unknown				
99☐ Others, Specify_____				

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

ADDITIONAL INFORMATION		
Medical/Surgical History		
Does the subject have any other clinically significant medical /surgical history? If Yes, provide the details below:	1☐ Yes 0☐ No	
Symptom/Diagnosis/ Procedure#	**Response**	**Medication (If Applicable)**
Diabetes Mellitus	1☐ Yes 0☐ No	
Hypertension	1☐ Yes 0☐ No	
Peripheral Vascular Disease	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Dyslipidemia	1☐ Yes 0☐ No	
Allergies	1☐ Yes 0☐ No	
Bronchial Asthma	1☐ Yes 0☐ No	
CAD (including Angina and MI)	1☐ Yes 0☐ No	
Others, Specify_____	1☐ Yes 0☐ No	
_____		

If the response to Medical History is checked as CAD, please provide previous management details:

Previous Management	Date	Details
☐ Medical Management	___ / _____ / _____ DD MMM YYYY	
☐ PCI	___ / _____ / _____ DD MMM YYYY	
☐ CABG	___ / _____ / _____ DD MMM YYYY	
☐ Others Specify: _____	___ / _____ / _____ DD MMM YYYY	

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Investigator Comments (if any)

_____

_____

Investigator Declaration

I cetify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.

Investigator Name : _____

Investigator Signature : _____ ____/_____/_____
DD MMM YYYY

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Follow up (1 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

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Site ID: | | | - | | | - | D |

Patient ID:_____

Follow up (6 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Protocol No: LA-RSH/103/2012

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Patient ID:_____

Follow up (1 Year)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		