Indian Council of
Medical Research

Dissemination Workshop on STEMI TN Project

Key words: STEMI: ST elevated Myocardial Infarction; PCI: Percutaneous Intervention;

Index

1. Preface

The STEMI India Protocol of STEMI (heart attack) care is a unique system for the treatment of heart attack developed by STEMI India. Unlike the western model of STEMI care which attempts to transport all patients with heart attacks to a major hospital for cardiac catheterisation and Primary PCI, the STEMI India Protocol combines the two strategies of Primary PCI and the Pharmaco-invasive strategy. This ensures that patients who are in rural areas and small towns are able to access state-of-the-art heart attack treatment. Furthermore, by utilising innovative technology and indigenously developed, IT-enabled and cloud-based ECG and monitoring devices, STEMI India has been able to overcome infrastructure and manpower deficiencies, to develop a world class system of care for STEMI.

The effectiveness of this model was validated in a pilot study – the Tamil Nadu STEMI Project – conducted in Tamil Nadu. This study was funded by the Indian Council of Medical Research (ICMR).

ICMR has now recommended the STEMI India Protocol as the model for heart attack management in India.

The two largest cardiology and physician scientific bodies in India, The Cardiological Society of India and the Association of Physicians of India,respectively, have joined STEMI India in endorsing this protocol and recommending it is as the ideal model for a national STEMI Programme.

STEMI India, a not-for-profit organisation, has been instrumental in developing this model and running a successful pilot project in Tamil Nadu. STEMI India has developed the unique 'STEMI Kit' (the STEMI ECG and monitoring device), algorithms for the management of STEMI, training modules for all participants in the STEMI Programme and has designed and developed the IT platform to run the entire system. The competencies gained by STEMI India in developing and running this programme have made it a unique organisation in the field of cardiology.

The STEMI India Heart Attack Programme is an outstanding example of a 'Make in India' programme, one that has the potential to save thousands of lives every year.

2. Background

2.1 ST-Elevation Myocardial Infarction – a killer disease

ST-Elevation Myocardial Infarction (STEMI) is the commonest and deadliest type of heart attack. STEMI occurs when blood flow stops to a part of the heart, and the heart is injured because it is not receiving enough oxygen. It is one of the largest contributors of death and disability in India.

Reperfusion is the restoration of blood flow to the heart. Early reperfusion minimises the heart muscle damage and preserves the pumping function of the heart, saving a patient from disability or death. Reperfusion within 90 minutes is optimal to save life in the event of a STEMI.

This project – the National STEMI Programme – aims to set up a dedicated and effective system for the treatment of STEMI patients across India.

2.2 STEMI in India

India has the highest burden of Acute Coronary Syndrome (ACS) patients in the world. Patients in India who suffer from ACS are younger (56.3 years) and have a higher rate (>60.6%) of STEMI than patients in developed countries. It is estimated that more than 3 million STEMIs occur every year in India. Since most of these patients are poor, less likely to get evidence-based treatments, and have greater 30-day mortality, reducing delays in access to hospital care and ensuring provision of affordable treatments could reduce morbidity and mortality.

2.3 Treatment of STEMI

There are three ways of reperfusion in STEMI. The earliest studies examined thrombolysis, initially with streptokinase and subsequently with tissue plasminogen activator (TPA) and its analogues. These are medicines that open up occluded arteries that can be given at any hospital. A meta-analysis of thrombolysis showed that this was a good way of reperfusion with improved outcomes across subsets except in the elderly and those delayed beyond 12 hours of symptom onset.

Subsequently, studies have shown the superiority of primary PCI – an alternative to thrombolysis – both in terms of efficacy and mortality. The US and Europe have used this as the basis for developing a STEMI system of care. Although these systems are effective, they are resource-

intensive and this approach pre-supposes the availability of a fairly evenly-distributed cath-lab density coupled with a good emergency medical services (EMS) system and physical infrastructure for transportation.

Multiple studies have subsequently shown that a strategy of routine and systematic catheterization, with PCI if indicated, within 24 hours of thrombolysis reduces the rate of re-infarction and is superior to the widely prevalent approach of thrombolysis followed by cath only for demonstrable ischemia – a strategy now called the pharmaco-invasive strategy.

3. Problems to be Addressed

There are two major issues in treatment of STEMI patients that can be addressed for immediate reduction in mortality and morbidity.

3.1 Optimal Treatment Strategy

Although Primary PCI has been shown to be superior to thrombolysis in terms of mortality and morbidity reduction, the infrastructure in India currently does not allow for all patients presenting with chest pain to be admitted to a cath-lab within 90 minutes of onset of chest pain.

With about 800 cath-labs and 3 million cases of STEMI in India, there are 3,750 STEMI patients per year for every cath-lab. Cath-labs may also be located at a significant distance from many villages, making it nearly impossible for a patient to reach it within the Golden Hour.

3.2 Reducing Time Delays

Saving lives due to STEMI or heart attacks calls for a system of care that facilitates diagnosis-to-treatment protocols within a specific time window. Despite advancement in STEMI treatment, the overall utilisation, system of care and timely treatment remains suboptimal. Rural India, in particular lacks reliable access to the healthcare required to prevent and manage a medical emergency such as STEMI.

More than one-half the mortality in acute MI occurs within 1 hour of the onset of symptoms. This "Golden Hour" is the best opportunity to salvage myocardium by reperfusion.

Most patients don't even reach the emergency department of a hospital within this hour. In order to remedy this situation, it is crucial to:

1. Reduce patient delay
2. Improve emergency medical system to deliver early therapy
3. Speedily transport the patient to a medical facility to deliver fibrinolysis or PCI

4.The STEMI India Framework

STEMI India has developed a protocol that addresses both the key problems in treatment of STEMI in India today. The framework involves rapid and accurate diagnosis and minimised door-to-balloon time as well as an optimal treatment strategy of combining primary PCI and the Pharmaco-invasive strategy of reperfusion depending on the location of the patient. This is now a coherent framework for developing a STEMI system of care suitable for India.

It is a hub-and-spoke model that uses an integrated healthcare network comprising

1. primary-care health clinics
2. small hospitals and
3. large tertiary-care facilities
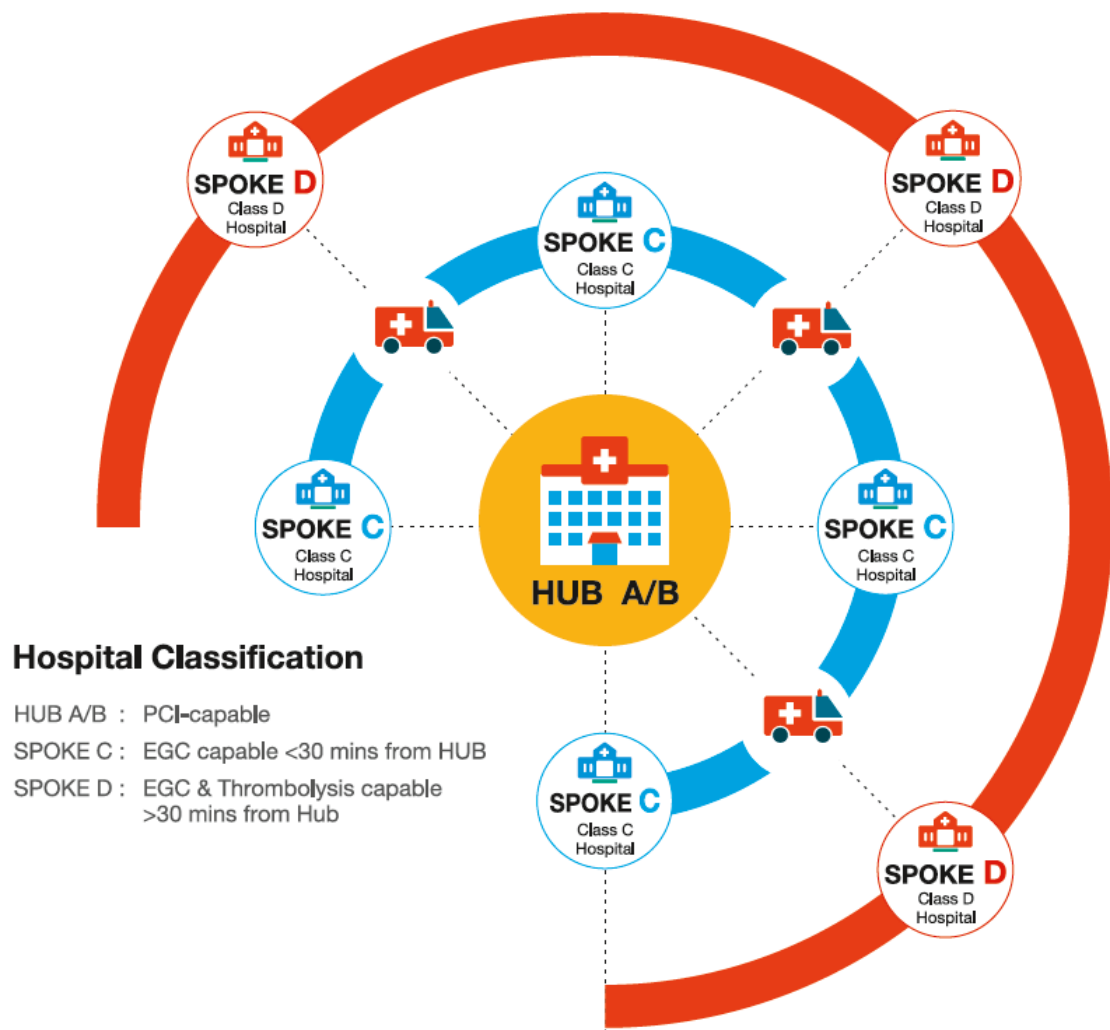4. an ambulance network linking all spoke hospitals to the hub

A STEMI Kit is installed in all ambulances and hospitals. It can record and transmit ECG and other vital signs. A team of experienced cardiologists is available on-call 24X7 to diagnose the ECG sent to their mobile phone through the STEMI India application.

4.1 Hub-and-spoke Model

The region covered under the STEMI India framework is divided into "clusters". Each cluster is made up of one of two types (Class 'A' or Class 'B') of city-based hub hospitals, and about 12 to 15 of two types (Class 'C' and Class 'D') of rural spoke hospitals, and a network of ambulances connecting these.

The emergency ambulance system (such as the GVK- EMRI) is activated by the patient or the healthcare facility by using 'CALL 108'.

Hospital Classification

HUB A/B : PCI-capable

SPOKE C : EGC capable <30 mins from HUB

SPOKE D : EGC & Thrombolysis capable >30 mins from Hub
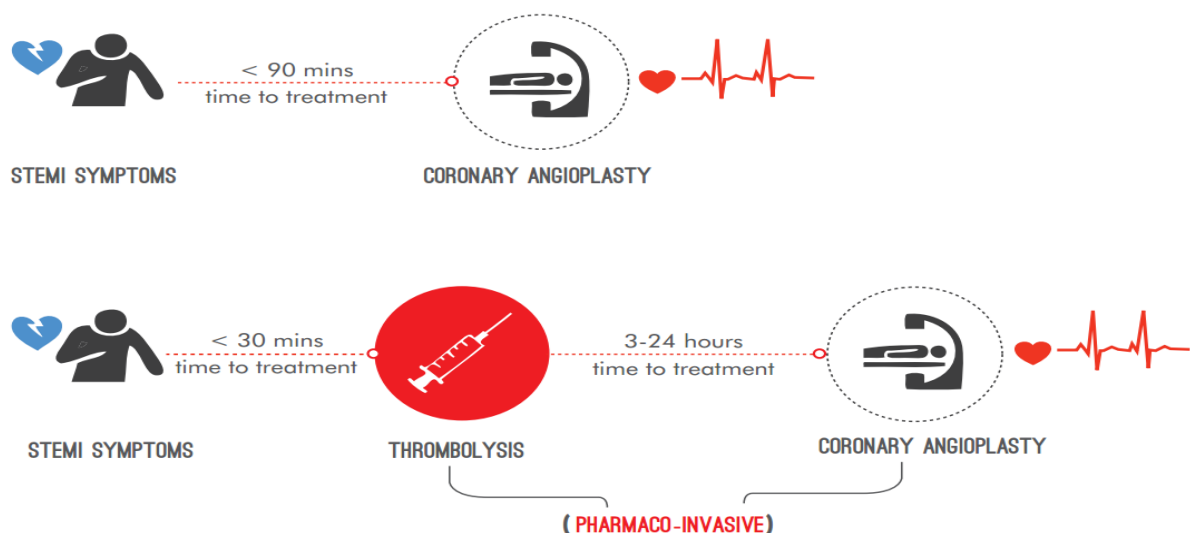
4.2 Protocol for Treatment

Standardised protocols describing the expected care delivery for a STEMI patient have been designed by STEMI India. Different protocols are implemented depending on the setting of care – i.e. emergency medical services, rural spoke hospitals, and PCI-capable hub hospitals.

The care at each of these locations is standardised to meet best practices.

Once STEMI has been diagnosed by the on-call cardiologist on his mobile phone through the STEMI India application.

1. Primary PCI is advocated for patients located close to catheterization laboratories - mostly patients in urban areas with short transportation times to hospitals with 24/7 primary PCI capabilities.

2. Patients in rural areas, with long transportation times to PCI-capable hospitals, will utilise the pharmaco-invasive strategy, of thrombolysis followed by catheterization and PCI if indicated, within 3-24 hours of thrombolysis.

Figure 2: Primary PCI and Pharmaco-Invasive Strategies

STEMI SYMPTOMS — < 90 mins time to treatment — CORONARY ANGIOPLASTY

STEMI SYMPTOMS — < 30 mins time to treatment — THROMBOLYSIS — 3-24 hours time to treatment — CORONARY ANGIOPLASTY

(PHARMACO-INVASIVE)

4.3 Technology Used

STEMI INDIA has developed an indigenous and affordable technology platform that empowers primary physicians/paramedics in rural and peripheral hospitalsto access immediate diagnosis of STEMI by an expert cardiologist.

It is a mobile device that consists primarily of:

- A 12-lead ECG monitor
- Vital signs monitors
- Data entry capabilities

- 2G/3G transmission capabilities
- GPS functionality
- An Automated External Defibrillator (AED) in all ambulances
- A printer

The STEMI India Mobile Application is installed in all STEMI Kits and the proprietary algorithm allows for instant diagnosis by the cardiologist-on-call and guides the physician/paramedic in following the STEMI India Protocol.

Figure 3: STEMI Kit Schematic

5. Pilot Project in Tamil Nadu

STEMI India concluded a yearlong pilot study in Tamil Nadu across 4 clusters. Pre-implementation data was collected on 906 patients and post implementation data on 1,561 patients.

Preliminary analysis of the data showed that:

- It is possible to establish a system of care in India by combining the two strategies – Primary PCI and Pharmaco-invasive.

- Pharmaco-invasive and Primary PCI have similar Mortality and MACE events, both significantly better than those of thrombolysis.

- Significantly greater number of patients utilised the superior strategy of Pharmaco-invasive therapy as compared to stand-alone thrombolysis – 13% to 20%.

- Significant numbers of the rural poor utilized the Below-Poverty-Line (BPL) insurance (0% to 60%) and were able to access the STEMI system of care and get best-in-class treatment of STEMI.

- The implementation of the STEMI India model of care produced an absolute mortality reduction of 4% (relative risk reduction of 20%) and an absolute MACE reduction of 5.5% (relative risk reduction of 16%

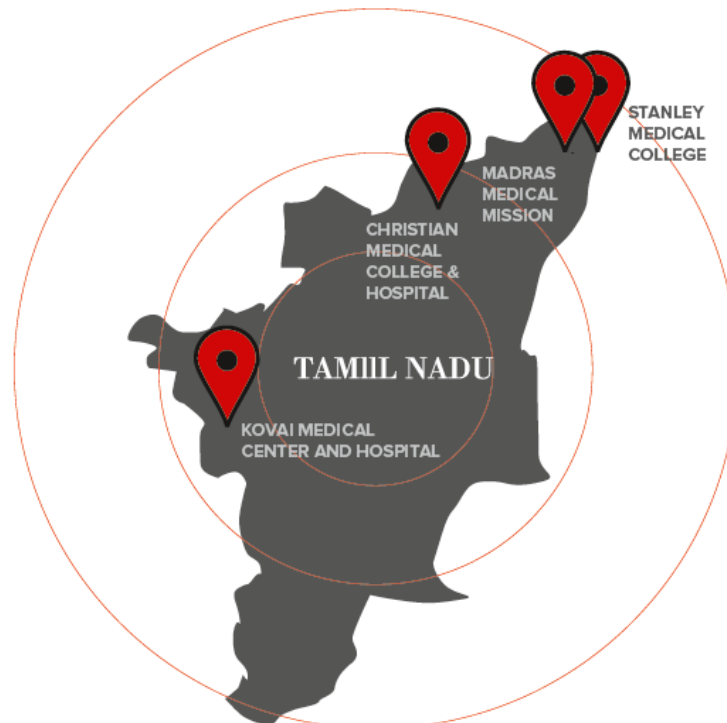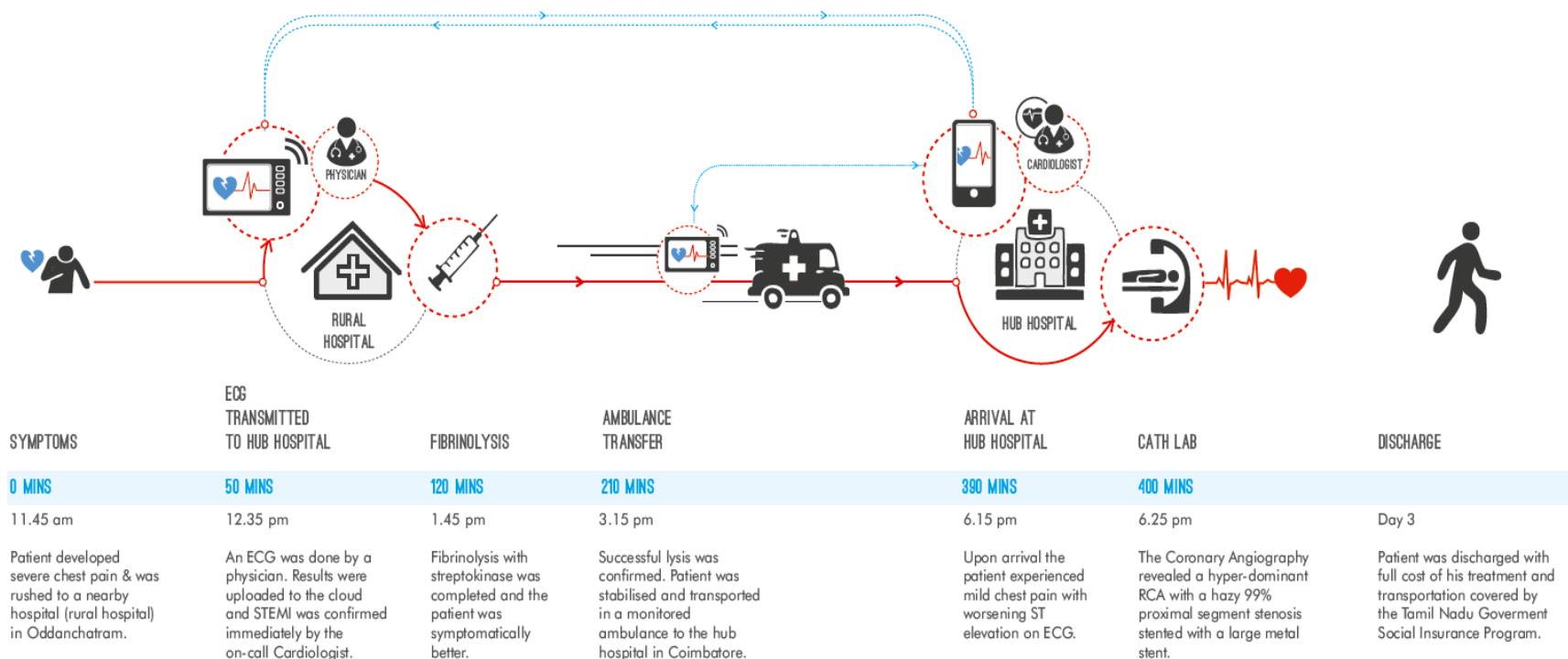*Figure 4:*

Clusters in

Tamil Nadu

Figure 4: TN Pilot Study: Sample Patient Journey

SYMPTOMS	ECG TRANSMITTED TO HUB HOSPITAL	FIBRINOLYSIS	AMBULANCE TRANSFER	ARRIVAL AT HUB HOSPITAL	CATH LAB	DISCHARGE
0 MINS	50 MINS	120 MINS	210 MINS	390 MINS	400 MINS	
11.45 am	12.35 pm	1.45 pm	3.15 pm	6.15 pm	6.25 pm	Day 3
Patient developed severe chest pain & was rushed to a nearby hospital (rural hospital) in Oddanchatram.	An ECG was done by a physician. Results were uploaded to the cloud and STEMI was confirmed immediately by the on-call Cardiologist.	Fibrinolysis with streptokinase was completed and the patient was symptomatically better.	Successful lysis was confirmed. Patient was stabilised and transported in a monitored ambulance to the hub hospital in Coimbatore.	Upon arrival the patient experienced mild chest pain with worsening ST elevation on ECG.	The Coronary Angiography revealed a hyper-dominant RCA with a hazy 99% proximal segment stenosis stented with a large metal stent.	Patient was discharged with full cost of his treatment and transportation covered by the Tamil Nadu Goverment Social Insurance Program.

6. Proceedings of Workshop

Dr Meenakshi Sharma of ICMR welcomed the august gathering and emphasised the importance of primary prevention while first targeting the low-hanging fruit of secondary prevention in Non-Communicable Diseases (NCD), specifically in Cardio Vascular Disease (CVD). The CREATE and the MACE registries clearly show the scope for reduction in Door-to-Needle and Door-to-Balloon times in India. 25% of patients are younger than 45, and the mean age for the first instance of MI is also much lower in India as compared to several developed countries. In order to ensure an evidence-based method is implemented as a system of care for heart attack in India, ICMR supported the STEMI India TN Pilot Project.

Dr Thomas Alexander, Director, STEMI India, outlined the agenda and stated that the aims of the workshop were to communicate the importance of STEMI management, explain the unique 'STEMI India' model and its medical and economic benefits based on the pilot TN STEMI Program, understand the process of implementation and commit to a plan and timelines for execution.

Dr DamodarBachani, DC (NCD), MoHFW, spoke of the UN's Sustainable Development Goal 3.4 that aims to reduce by a third pre-mature mortality due to NCD. He then elaborated the steps taken under the National Program for reduction of Cardiovascular Disease, including hiring additional MDs, setting up cardiac care centres, and developing training modules as well as algorithms for the treatment of MI and hypertension. He stated that a National STEMI Program could be set up and each state could adopt it based on a Project Implementation Plan (PIP) drawn up specifically for that state.

Dr SowmyaSwaminathan, Secretary, DHR and DG, ICMR, stressed on the importance of measuring the burden of disease in each state, considering how heterogeneous our country is. ICMR is conducting several studies to study risk factors such as hypertension, diabetes, tobacco use, diet patterns and exercise levels in order to promote primary prevention such as higher taxes on sugar and tobacco. She spoke of ICMR's aim to fund evidence-based research and to recommend effective models.

Dr Ajit Mullasari, Director, STEMI India, spoke about the burden of cardiovascular disease in India, of how increasingly younger patients are being affected, and gaps in STEMI Management in terms of lack of early diagnosis and appropriate treatment strategies. Only 1.2% of the GDP of India is allocated to Public Health Spending coupled with a critical

shortage of doctors and other health care workers, together significantly affecting health care delivery in India.

While the absolute number might not be important, the available funds must be utilised for the maximum benefit. Several schemes such as the Janani Suraksha Yojana, the National Health Mission, the Rashtriya Swasthya Bima Yojana and the Jan Aushadhi are steps in the right direction. It is estimated that there are over 2.5 million cases of STEMI in India annually, translating to 1,500 to 2,000 per million of the population affected annually.

The CREATE registry demonstrates that the poor are disproportionately affected, and have higher mortality due to inadequate access. He concluded that the development of a STEMI system of care, that is equitable and accessible, should be a priority area in cardiovascular care in India.

Dr L M Nath and Dr Dhaliwal, who chaired the session, concluded that the will to make a difference has to translate into action, and that a National Policy for heart attack care will be laid down. Dr Ravinderthen thanked the all the attendees.

Dr Thomas Alexander, Director, STEMI India initially discussed the three modes of reperfusion therapy – standalone thrombolysis, primary PCI and the Pharmaco-invasive mode of reperfusion. He showed data, both international and Indian, to show that Primary PCI and the pharmaco-invasive strategy of reperfusion were the superior strategy and similar in their results.

He then described the 'STEMI India Model' that combines these two strategies, of Primary PCI and Pharmacoinvasive strategy, in a 'Hub and spoke' model. The Classic STEMI India model has two types of Hub hospitals – A, with 24/7 cath lab availability and B, with limited time cath lab availability – where primary PCI is done for patients directly presenting to these hospitals. These are linked to peripheral spoke hospitals, where thrombolysis is fdone and the shifted within 3-24 hours to the hub hospital for invasive treatment.

The tree critical elements of the successful model were

1. Utilisation of the unique 'STEMI Kit' for early diagnosis of STEMI at remote spokes by ECG's transmitted to the hub and diagnosed by the 'on call' cardiologist. These "STEMI Kits" – a Multifunctional 12-lead ECG-integrated multi-parameter monitoring unit with data entry capability – are installed at hospitals and ambulances. The management algorithms and data entry, stored in the cloud, is also done using the same device.

2. Utilisation of the BPL insurance to ensure that every patient is able to access the STEMI care.

3. 108 Emergency ambulance services

The TN Pilot Project data – which has been accepted for publication in JAMA Cardiology - shows that the STEMI India model reduces mortality by 20% relative to the no-intervention case (3% absolute reduction). This has been primarily derived from the change in practice in the spokes of standalone thrombolysis to the pharmacoinvasive strategy. Apart from this there have been improvement in the other time related metrics.

The three different models that can be utilised in areas of a state depending on the geographies, manpower and available facilities – private or public – were elucidated. Thus the model utilised in a 'STEMI Cluster' could be a Classical hub and spoke model, a Dual-Hub Model or a Two-Tier – model.

The World Heart Federation, at its lrecent meeting in Mexico had recommended the STEMI India model as ideal for low- and middle-income countries in Mexico last year.

Mr GajananNagarsekar from Kallows Engineering and .. from Maestros Technologies demonstrated the workings of the STEMI Kit – a multifunctional 12-lead ECG-integrated multi-parameter monitoring device developed by Kallows according to STEMI India's specifications, allowing participants to see the technology used in the TN STEMI Pilot Project firsthand.

Ms Shoba and Dr Justin Paul from the Tamil Nadu Health Systems Project spoke of the infrastructure available in Tamil Nadu, and of plans to install 16 more cath labs in government hospitals in the State and to provide more training. Connected by the hub-and-spoke model to rural hospitals and catered to by the 108 ambulance network, these will increase access to government care for all patients with chest pain.

Ms Varshini of STEMI India, explained the 4 steps involved in program rollout and implementation as well as timelines for each.

o Step 1 involves mapping the region,identifying the hospitals, classifying them and forming the clusters.

o In Step 2, agreements are drawn up, personnel are hired and the devices are procured.

o Step 3 includes 4 Phases – installation of the devices, training on device use, base-case study, and training on the protocol

o Step 4 is the final stage of implementation when monthly training

continues, periodic reports are generated and the model is running efficiently.

Dr Muraleedharan, Professor of Economics, IIT Madras, presented the Cost Effectiveness Analysis of the TN STEMI Pilot Project. According to WHO standards, 3 ratios are measured:

o Cost-Effectiveness Ratio – with 81 lives saved out of 2,500 due to the STEMI India Model as compared to the base-case, on a spending of Rs. 1.7 cr annually, the Cost-Effectiveness is about Rs. 2 lakh per life saved.

o Cost-Utility Ratio – with 1,500 life-years saved, the Cost-Utility is about Rs. 11,000 per life-year saved.

o Cost-Benefit Ratio – considering the present value of all future income of the extra lives saved, Rs. 6.2 cr is the annual saving to the economy due to the protocol. This translates to Rs. 3.58 gained per rupee spent.

He concluded that the realistic benefit gained of Rs. 4 per rupee spent, and the relative reduction of 21% in terms of mortality alone, as compared to no intervention, was a highly effective use of resources. In addition, when reduction in morbidity is considered, the model becomes even more effective.

Dr Ramana Rao, Head, EMLC & Research-GVK EMRI, then spoke about the role of emergency services in the TN STEMI Project and how the 108 ambulances enabled timely access to medical resources. With systems and processes in place, the 108 ambulance network was able to significantly reduce response times – Average Handling Time of 3 mins, Response Time of 15-25 mins and Scene to Hospital Transfer in 30 mins.

Dr NitishNaik, AIIMS, spoke of the MACE registry and how electronic data entry in all participating hospitals will enable accurate metrics and allow for evidence-based treatment strategies for all ACS patients. Integrating the data collected via the STEMI Programme would enable this as well.

Dr Rajeev Gupta, EHCC Jaipur discussed plans to start a similar STEMI programme in a private hospital in Rajasthan.

A round-table discussion followed, when questions were addressed and the points laid out in the following section were agreed upon

7. Summary

1. The 'STEMI-India Model' of STEMI system of care, a unique system of care that combines the two reperfusion strategies of pharmaco-invasive treatment and Primary PCI, has shown a significant reduction in mortality and major adverse cardiac events (MACE) in the implementation phase as compared to the pre-implementation phase in the Tamil Nadu (TN) STEMI Program.

2. The 'Economic evaluation' indicates that STEMI India Model is efficacious, effective and cost-effective as compared to the "no intervention" case.

3. The 'STEMI-India Model' of STEMI system of care, which has been endorsed by the Cardiological Society of India and the Association physicians of India, is a good model for a STEMI system of care in some states in India. In other states, the alternative models proposed by STEMI India team can also be considered.

4. Depending on the geographic mapping, manpower mapping and facility mapping, the model chosen for a particular area could be a classic STEMI cluster – single hub with multiple spoke model, a dual hub model or a two tier STEMI cluster model.

5. The STEMI Kit - a Multifunctional 12 lead ECG integrated multi-parameter monitoring unit with data entry capability – which was used in the TN STEMI program, significantly helped to improve the diagnostic accuracy of STEMI and the quality of data capture. Many of these data entry in real time helped in quality improvement.

6. The role of GVK EMRI 108 ambulance service was critical in the success of the TN STEMI Program.

7. Patients from the lower socio-economic strata with ACS (Acute coronary syndrome) have a higher percentage of STEMI, use less evidence based treatment and have a higher mortality. STEMI care can be delivered to this class of STEMI patients through a government insurance scheme.

8. STEMI India has developed the model, run the TN STEMI program, developed the STEMI Kit with its partners and has developed the software to run the program. It has also developed unique competencies to run similar programs in other states.

9. The proposal for up scaling of this project supported by ICMR into other states through a dissemination workshop is a good example of how translation of research findings can be undertaken to deliver goods of public health importance.

8. Recommendations

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

2. The states should prepare Project Implementation Plan under NHM along with Costing of the project for implementation in their respective states. The NCD cell at MOH&FW and ICMR will provide support in this activity.

3. STEMI India investigators will provide states '**Costs for Implementation of STEMI**'.

4. The STEMI India Team may be contacted by states for providing App for geographical mapping, facility mapping ,etc. Once mapping is done by the state, data may be provided by states to STEMI India Team in prescribed format for developing a state specific STEMI model.

5. The STEMI India team will train state representatives in using STEMI kit.

6. As 108 ambulance service is critical in the success of the STEMI Program, any state planning a STEMI system of care in the state, should have a state-wide ambulance service in place, similar to this. Other states may initiate steps to take up 108 ambulance services in their states.

7. To deliver STEMI care that is both accessible and equitable to those from the lower socio-economic strata, it is essential that a BPL insurance program, similar to the CM Health insurance scheme in Tamil Nadu, be put in place prior to starting a STEMI program in states where this scheme is non-existent. States with similar schemes can move forward with the STEMI program.

8. Ownership of the STEMI system of care should be with the State Government. The program would be funded by the State Government.

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

10. Sincere attempts may be made to combine the MACE registry, that is run by ICMR, with the STEMI database so as to improve its coverage. The ICMR will provide the software for data collection free of cost to states. The confidentiality of data will be maintained by ICMR and analysis of data submitted by hospitals participating in STEMI care program versus all India data will be provided to hospitals. This will help in building up a surveillance mechanism and assessing the impact of STEMI care program.

Annexure

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