CLINICAL INNOVATORS

Interview by BRAHMAJEE NALLAMOTHU,

STEMI Systems of Care in India: A New Paradigm for Treatment

An Interview with Thomas Alexander, MD, and Ajit Mullasari, MD

ystems of care have drastically altered the way patients with ST-elevation myocardial infarction (STEMI) are treated in the United States and Europe. In this context, "system" refers to an integrated group of separate entities within a region that rapidly provide coordinated services across the continuum of care—from patient entry to discharge, and encompassing emergency medical services, community and tertiary hospitals, and payers. Many of these programs have demonstrated great success in both use and timeliness of reperfusion therapy, prompting recent clinical practice guidelines to broadly recommend this approach for STEMI patients.

Unfortunately, such triumphs have not been the same for STEMI patients in low- and middle-income countries, like India, where acute coronary syndromes (ACS) now contribute to a rising toll of death and disability. Reasons behind this growing epidemic in India include longer life expectancies, rises in chronic diseases like diabetes mellitus and obesity, and increasing tobacco use and air pollution. Tragically, the incidence of STEMI-associated deaths is rising in India just as novel therapies and STEMI systems of care may be curbing its impact in Western countries. Recent policy changes, however, may be providing new opportunities to address existing barriers for STEMI systems of care in India.

I spoke recently with **Thomas Alexander**, **MD**, and **Ajit Mullasari**, **MD**, cardiologists in the



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southern Indian state of Tamil Nadu. Both are involved with launching an innovative and sustainable system of care that will expand access to reperfusion therapy within a population catchment area of tens of millions. This large-scale implementation program, supported by the Indian Council of Medical Research, leverages: (1) new data on STEMI therapies; (2) a novel, Indian-based information technology platform built into the clinical flow process; (3) a budding emergency med-

ical services system in India; and (4) an expanded, statewide social insurance program for vulnerable populations. If successful, the cost-effective approaches used in India could have implications for not only other low- and middle-income countries but for Western health care systems as well.

With all of its other healthcare needs and priorities, why focus on reperfusion therapy in India?

Dr. Alexander: Coronary artery disease (CAD) is a major contributor of death and disability in India, and its overall prevalence has risen considerably in recent years. It is now estimated that about 5% of Indians in rural areas and 10% in cities have CAD. The most complete data about STEMI in India come from CREATE, a large clinical registry of ACS patients from 89 hospitals in 10 regions across India.

Among the more than 20,000 patients in CRE-ATE, over 60% had STEMI. That increased to 70% when poorer patients are taken into consideration. It also turns out that more than one-third of STEMI patients were younger than 50 years of age. We are now seeing more and more patients in their 20's and 30's—something unheard of in the West. In addition, patients affected during their working years may disrupt a family's financial situation. Sadly, despite these statistics, treatment of STEMI in India falls far behind the level of care provided for patients in other countries. Patients rarely present in a timely manner and there are too many that receive inadequate therapies.

Can you explain what currently happens to a poor patient in India who suffers STEMI and how your program changes this story?

Dr. Mullasari: Based on some of our pilot data from the Tamil Nadu-STEMI program, we have found that about 20% of STEMI patients in India who present to a rural hospital or clinic are not given reperfusion therapy, mostly because they arrive beyond the window when treatment can be started. Of the 80% who receive reperfusion therapy, it is frequently a single dose of streptokinase. That's typically the end of treatment (regardless of whether it is successful or not). Most patients are unable to go to a hospital with a cath lab, as most of these facilities are urban-based and too far to travel for patients given expenses.

Dr. Alexander: We are hoping our program will change this approach. Let me share with you the story of one of our first enrolled patients: Mr. P was a 43 year-old smoker who lived in a small rural town working, when he could find work, as a farmhand to support his wife and family. Fortunately, he was enrolled in the social insurance program recently promoted by the Tamil Nadu state government for its below-poverty-line citizens.

On June 16, 2013 at 11:45 AM he developed severe chest pain and was rushed to a nearby hospital, which had recently been included as a "spoke" in the STEMI cluster associated with the city Coimbatore, and an ECG was done at 12:25 PM. ECG results were immediately uploaded to the cloud using a novel STEMI device developed for this program; the on-call cardiologist at the hub hospital in Coimbatore confirmed STEMI at 12:35 PM. By 1:45 PM, fibrinolysis with streptokinase was completed and the patient was symptomatically better, and successful lysis was confirmed, at 3:15 PM.

The patient was stabilized and monitored in this rural hospital until an ambulance was able to transport him to Coimbatore. Every 15 minutes, the STEMI device transmitted a screen shot of the patients Spo2, heart rate, ambulatory BP, and ECG to the destination hospital. Upon arrival, the patient was experiencing mild chest pain with some worsening ST elevation on ECG. Coronary angiography revealed a hyper-dominant RCA with a hazy 99% proximal segment stenosis (which was later stented with a large bare metal stent). The patient was discharged 2 days later with the full cost of his treatment and transportation paid for by the social insurance program. Prior to this program, the patient would likely have been discharged from the rural hospital after 3 or 4 days, with a lesion that had a very high risk of acute re-occlusion.

The STEMI device sounds fascinating. How did you get the Indian partners to develop the IT platform and software, and at what cost?

Dr. Alexander: We have two technology partners: one is a software partner who developed the software and the other is a technology partner who developed our STEMI Device. In early 2011,

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we were looking to develop a device that could perform ECGs at a remote location and transmit them to a hub hospital. We came across a company, called Maestros, from Mumbai that seemed to have a device that fit our needs. Their team who agreed to fly down and demonstrate it; a week later they showed us a device almost exactly our specifications. From there we moved on to modifying the device to the present multi-functional device, which includes an ECG machine, monitoring device, and a data entry device—all three in one. The cost of the device is \$1,750, and we've acquired 40 devices, with the potential to drop these costs by two-thirds in the future.

The software was developed by a company, Aosta from Coimbatore, who worked with the workflow and algorithms involved in treating a typical STEMI patient. Initially, we had institutional resources for software development but they fell through. I realized, though, that there was no turning back now. I just opened briefcase, took out my checkbook, and handed the Aosta representative a personal check for \$10,000. I told him, "This project may eventually fail due to many reasons, but it won't be because of lack of money."

To us, this was a symbolic but irrevocable first step towards developing a STEMI system of care in India. I was willing to use my own money if needed to start this process. Subsequently, we have been promised funding from the Indian Council for Medical Research and many others have come forward to put money into STEMI India, a not-for-profit organization started by myself and Dr. Mullasari to develop STEMI care in India.

It seems as if several external events had to fall in place for this program to work. Can you tell me about your partners within the social insurance program and the EMS system?

Dr. Mullasari: Patients from the lower socioeconomic strata in India bear a higher burden of STEMI both in terms of number and poorer outcomes. Furthermore, the percentage of these patients having access to definitive treatments that include revascularization is abysmally low. Any program that is not inclusive particularly with regard to those from the lower socio-economic strata would fail to address this very important issue.

The Tamil Nadu Health Systems Project is a social insurance program tailored to address this issue in these vulnerable populations. These programs have now developed in India in select states and cover various services. The Tamil Nadu state government has worked with us to actively determine the best therapies for STEMI patients. The social insurance program is administered by xx and covers services as part of a "bundle" that includes initial therapy with fibrinolysis or PCI as well as other needed treatments. The bundle also includes costs of transfer to a "hub" hospital, if needed, and a pharmacoinvasive approach with PCI.

The GVK Emergency Management and Research Institute (EMRI) is the largest emergency medical service provider in India today. It is one of the great success stories of recent times in medical care in India, as just a decade ago there was essentially no ambulance system available in India. It is a not-for-profit organization that provides free basic medical services and transportation through the "108" Emergency Service Line that is analogous to "911" in the United States. It has nearly 4,800 ambulances across 14 states and regions of India. GVK-EMRI has been a very engaged partner in this program. The STEMI device is now incorporated on to their ambulances for this pilot project. They also have opened up "inter-facility" transfer for STEMI patients, which was not permitted earlier. This has helped the pharmacoinvasive approach to be used in this STEMI project.

What have been the biggest challenges so far to rolling out your program and what will be the largest threat to sustainability that you see in the near future?

Dr. Mullasari: We always say that the building blocks for a workable model were already developing: the social insurance program, the GVK EMRI ambulance system. The challenge was to put them together, and every step is difficult in India! Although a number of challenges remain, we believe the key to the success of this program is to continue to have the state government on board.

For this to roll out nationally, the STEMI program has to grow state by state. This is largely because health in India remains a state-level subject. However, developing STEMI systems of care will also require the help of other key stakeholders including local cardiology societies and the public. We are hoping that data from our program can help identify areas in which we can improve the system further and also serve as a framework for others who are hoping to develop similar models in their regions.

You both seem optimistic about the future—are cardiologists and other providers beginning to buy-in to this program? What has been the reaction from healthcare policymakers and bureaucrats?

Dr. Alexander: Every time we present this project at cardiology meetings in India or abroad now, we get such an enthusiastic response and so many people commenting that this is such an important need for this country. We also get a lot of cardiologists, many of them youngsters who have just finished their training in internal medicine or cardiology, asking if we could help them to start a similar program in their region or city. This is really energizing for us. But, unfortunately, this wasn't always the case.

Initially, it was very difficult and depressing because things like this move slow in India and there are so many reasons that we were told why this would not work. Many cardiologists saw the need and potential but were naturally skeptical given the challenges facing the public health sector in India. We have written literally hundreds of letters and emails to government officials without receiving even an acknowledgement. Some of this is a deeply entrenched in (often accurate) suspicion that private initiatives in India have some hidden and nefarious agenda—mostly targeted at making some easy money.

After a number of attempts and a few chance meetings to explain the project, one senior bureaucrat in the health ministry called us for a meeting. Once convinced about the genuineness of the project and the powerful data supporting the use of these treatments in STEMI patients, the ministry turned pro-active and now is pushing the project vigorously especially in getting the public hospitals to be part of this program. This will be a big step because once there is a successful example out there it will be easier for others to rally around.

What do you think STEMI systems of care in Western countries could learn from your program?

Dr. Alexander: I think there are several lessons that we can share with others. Most importantly, I think we have tried to use newer IT platforms and technology to overcome infrastructure and manpower constraints. Our partners have helped to develop a STEMI device and software to connect a network of hospitals in India. There is already a precedent for this "reverse" innovation as new, low-cost ECG and ultrasound devices for developing countries are being introduced in the United States. For those of us who know India well, the possibility that STEMI systems of care would have happened is impossible to imagine even 10 years ago. These lessons might have great relevance for some rural parts of North America and Europe where access to cath labs and cardiac surgery may be limited and soaring health care costs are challenging even the resources that provide these services. Recent data, particularly from the STREAM trial by **Paul Armstrong, MD,** and others, has shown that a pharmacoinvasive approach is an effective strategy for reperfusion and comparable to primary PCI. This is a critical insight as it places much less strain on the transportation issue in countries like India, which can be prohibitively expensive. Our model for STEMI care combines affordable technologies with a pharmacoinvasive approach to develop a workable and less-resource intensive model.

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