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Honorary Editor : Dr. Keyur Parikh



From the Desk of Hon. Editor:

Dear Friends,

The field of percutaneous coronary intervention remains extremely active, with major advances involving revascularisation strategies and techniques, adjuvant antithrombotic therapy (with a particular emphasis this year on the optimal duration of antiplatelet therapy after drug-eluting stent stenting), concerns regarding the importance and risks of bleeding and methods to decrease those risks and a strong focus on the study of newer generation drug-eluting stent and bioresorbable/bioabsorbable scaffolds devices with some concerns regarding the safety of the later. Given the improved clinical outcomes of newer generation drug-eluting stent, comparisons between these and coronary artery bypass graft surgery are important. At the same time we should not forget enormous advances in Percutaneous Valve Replacements. Thoracic Endovascular Stent Grafting, Endovascualr Interventions, Structural Heart Interventions, Electrophysiology Advances and so on . At CIMS Hospital, we are pioneers in almost all the percutaneous multi modality interventions that are done in India. This article gives a brief synopsis and update in the area of Coronary Artery Intervention.

- Dr. Keyur Parikh

The year in cardiology 2016: Coronary Intervention (Part-2)

The last issue gave information about novel devices used in percutaneous coronary intervention including drug eluting stents, bioresorable scaffolds and reducer stents.

This issue includes information about Rotablator, Fractional Flow Reserve, Intravascular Ultrasound.

The cardiology team at CIMS pioneered for NEOVASC(a reducer stent)study which was a multicenter, nonrandomized, open-label prospective study that evaluated the safety and feasibility of the Coronary Sinus Reducer. The results at 10 years follow up were presented at Society of Cardiac Angiography and Interventions (SCAI) conference in Orlando, US 2016. A research manuscript was also published in reputed international Journal of American College of Cardiology.

<u>Title: Coronary Sinus Reducer Stent for</u> <u>the Treatment of Chronic Refractory</u> <u>Angina Pectoris</u>

A Prospective, Open-Label, Multicenter, Safety Feasibility First-in-Man Study

Keyur H. Parikh, Shmuel Banai, MD, Shmuel Ben Muvhar, MD, Aharon Medina MD, Horst Sievert, MD, Ashok Seth, MD, Jonathan Tsehori, MD, Yoav Paz, MD, Ami Sheinfeld, MD, Gad Keren, MD

Other novel procedures adopted by interventional cardiologists at CIMS and world over include

d) Rotablator: Rotablation represents an additional to the standard Percutaneous Transluminal Coronary Angioplasty (PTCA) procedure. While a standard PTCA procedure is limited to the use of balloons and stents, rotablation also uses a tiny drill, powered by compressed air, to remove calcified deposits. Rather than increasing luminal diameter by arterial stretching and plaque fracture as with balloon angioplasty, rotablation debulks atherosclerotic plaque. The basic physical principle is differential cutting. It is usually followed by balloon angioplasty, and the implantation of one or more stents. A rotablator is a miniature drill capped with

Cardiologists

Cardiologists						
Dr. Satya Gupta	(M) +91-99250 45780	Dr. Milan Chag	(M) +91-98240 22107			
Dr. Vineet Sankhla	(M) +91-99250 15056	Dr. Urmil Shah	(M) +91-98250 66939			
Dr. Vipul Kapoor	(M) +91-98240 99848	Dr. Hemang Baxi	(M) +91-98250 30111			
Dr. Tejas V. Patel	(M) +91-89403 05130	Dr. Anish Chandarana	(M) +91-98250 96922			
Dr. Gunvant Patel	(M) +91-98240 61266	Dr. Ajay Naik	(M) +91-98250 82666			
Dr. Kevur Parikh	(M) +91-98250 26999					

Congenital & Structural Heart Disease Specialist

Dr. Kashyap Sheth (M) +91-99246 12288 Dr. Milan Chag (M) +91-98240 22107 Dr. Divyesh Sadadiwala (M) +91-8238339980

Cardiothoracic & Vascular Surgeons

Dr. Manan Desai	(M) +91-96385 96669
Dr. Dhiren Shah	(M) +91-98255 75933
Dr. Dhaval Naik	(M) +91-90991 11133

Pediatric & Structural Heart Surgeons Dr. Shaunak Shah (M) +91-98250 44502

Cardiovascular, Thoracic &

Thoracoscopic Surgeon

Dr. Pranav Modi (M) +91-99240 84700

Cardiac Anaesthetists

Dr. Chintan Sheth (M) +91-91732 04454 Dr. Niren Bhavsar (M) +91-98795 71917 Dr. Hiren Dholakia (M) +91-95863 75818

Cardiac Electrophysiologist

Dr. Ajay Naik (M) +91-98250 82666 Dr. Vineet Sankhla (M) +91-99250 15056

Neonatologist and Pediatric Intensivist

Dr. Amit Chitaliya (M) +91-90999 87400 Dr. Snehal Patel (M) +91-99981 49794





Rotablator system for hard calcified lesions

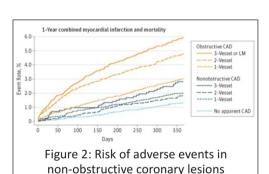
an abrasive, diamon d-studded burr. The rotablator is used in a type of catheterbased procedure called rotational atherectomya minimally invasive treatment that is sometimes used to pulverize hardened plaque within a coronary artery. Rotablation represents one of the alternative devices to treat complex coronary artery stenosis. As interventionists treat older patient populations with more advanced, complex, and calcified disease, the potential role of rotational atherectomy has increased

At CIMS, Rotablator is used when:

- The plaque is felt to be too difficult to flatten against the artery wall with just PTCA.
- The plaque appears to have a large amount of calcium present in it and does not move easily.
- The plaque is too long or starts where the artery begins.
- The artery has too much plaque, which needs to be removed before another procedure.
- The artery is felt to be small for other procedures.
- A PTCA and/or stent has been done before and the lesion has reclosed.

New Pathophysiologic Insights In a) Fractional flow reserve (FFR) **Coronary Artery Disease**

Maddox et al. compared the rates of allcause mortality and myocardial infarction in patients with non-obstructive coronary artery disease (n = 20 899), obstructive coronary artery disease (n = 8384), and no apparent coronary artery disease (n = 8391). Non-obstructive coronary artery disease (defined as ≥ 1 stenosis $\geq 20\%$ but no stenosis \geq 70%), compared with no apparent coronary artery disease (no stenosis >20%;) was associated with a significantly greater 1-year risk of myocardial infarction and all-cause mortality (FIG 2).



These data confirm the prognostic importance of 'mild lesions', which is consistent with the previous observation that many infarctions are related to sites of modest luminal obstruction. The risk of adverse outcomes increases with the extent of obstructive but also nonobstructive coronary artery disease.

Plaque Imaging In Coronary Artery **Disease**

Plaque imaging plays a critical role in decision making process in cardiology clinical practice.

Myocardial FFR is an index measure functional severity of coronary stenosis which is useful in assessing whether or not to perform angioplasty or stenting on "intermediate" blockages. It is a guide wire-based procedure that identifies culprit lesion in case of disease. It has the multi vessel advantage of being independent of changes in heart rate, blood and contractility pressure, accounting collateral flow.

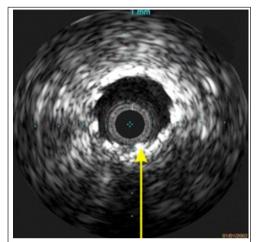


b) Intravascular Ultrasound (IVUS)

Cardiologists at CIMS observe images inside the heart coronary arteries to assist in diagnosis. IVUS offers a tomographic, 360-degree view of the arterial wall



from the inside, allowing a more complete and accurate assessment than is possible with angiography.



IVUS show proper placement and apposition of stent

At CIMS, IVUS is used to determine both plague volume within the wall of the artery and/or the degree of stenosis of the artery lumen. It can be especially useful in situations in which angiographic imaging is considered unreliable; such as for the lumen of ostial lesions or where angiographic images do not visualize lumen segments adequately, such as regions with multiple overlapping arterial segments. It is also used to assess the effects of treatments of stenosis such as with hydraulic angioplasty expansion of the artery, with or without stents, and the results of medical therapy over time.

Robotics in the Cath Lab

Robotic-assisted PCI continues to head interventional cardiology. In 2015-2016 the first conference dedicated to teaching

robotics for complex PCI was held. Robotics is a critical tool for performing complex PCI giving physician's a robotic precision, protection from radiation exposure, and the ability to sit comfortably without the need for lead shields. These factors are especially important in complex PCI procedures that not only require a high level of precision but also tend to be longer and require more radiation.





Another contribution this year was the FDA approval of the CorPath Vascular Robotic System for radial access PCI. Robotics can play an important role in radial procedures, offering the same benefits of radial access for patients while protecting physicians from additional radiation exposure. For all PCI's, robotics can enable the entire cath lab team to

reduce their radiation exposure but taking a few simple steps.

Myocardial Revascularization

With improved clinical outcomes of newer generation drug-eluting stent, comparisons between angioplasty and Coronary Artery Bypass Graft (CABG) surgery remain controversial and critical. The BEST trial randomly assigned 880 patients with multi-vessel disease to either PCI with everolimus-eluting stents or CABG surgery. At median follow-up of 4.6 years, major adverse cardiac events in the PCI group were higher than CABG group (15.3 vs. 10.6%, P = 0.04), driven by a reduction in repeat revascularization and spontaneous myocardial infarction in the surgical group, reaffirming the role of CABG surgery in management of patients with multi-vessel disease in comparison to newer drug-eluting stents.

Conclusion

Current advances in coronary intervention aim primarily at perfecting long-term results, with the premise that bioresorbable scaffolds will eventually replace metallic drug-eluting stents. However, the short-term incremental benefit of technical advances or device iterations becomes increasingly difficult to demonstrate. Today, improved outcomes largely depend on defining the optimal synergy between best medical care and device-based therapies in the individual patient.



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The Future of Cardiothoracic Surgery... Dying Star or Supernova?

An interesting article by Dr. Edward D. Verrier M.D. Published in AATS recently

We have all heard of the imminent death of cardiothoracic surgery as a medical specialty. The field had its meteoric rise and now is on the rapid descent. Adult cardiac surgery is being taken over by Cardiology, adult thoracic surgery is really not a sustaining specialty unto itself, and congenital heart surgery should only be centralized in a few small centers. Like many rumors there may be some half-truths in those assertions but in the current reality of modern medicine it is highly unlikely that cardiothoracic surgery will flounder for long or fade away completely.

If one steps back and tries to look at cardiothoracic surgery in the broadest historical perspective, the specialty is still in its infancy... still going through its growth spurt... still looking for the sustaining equilibrium. Since the first durable thoracic operative procedures in the 1930s, and the first open cardiac procedures in the 1950s, we have only been around as a specialty for a little over 50 years. We were initially a small, highly focused, very professional group of surgeons exploring the boundaries of science, surgery, research, and ethics; we were mostly focused on lung cancer and congenital heart disease. Our specialty was then subsequently fueled by a new, remarkable technology (cardiopulmonary bypass) which allowed reconstructive work within and on the heart in an essentially bloodless, motionless field. This new technology occurred at a time when first, compliance issues and human research oversight was minimal compared to current standards, and secondly, a huge untapped population of patients with atherosclerotic coronary artery disease was discovered. Coronary bypass surgery evolved and fostered an explosive growth and also allowed us to attract the best and brightest of young surgical residents. The downside of this remarkable growth was a change in perception of our specialty as a "profession" into one simply driven by business and market forces (a "commodity"). We maintained our security for over two decades until our equanimity was shaken by new, less invasive, endovascular technology that we no longer controlled: non-surgical approaches to coronary disease, some congenital disease, and with the potential to even threaten our exclusive bastion, valvular heart disease. The pendulum swung away and change occurred.

The STS cardiothoracic database is solid, extensively used and has become a benchmark for specialty / professional outcomes analysis. We have initiated our own NIH sponsored prospective surgical clinical trials (NETT, REMATCH, STITCH) which have been published and have established well accepted clinical guidelines . We are involved as surgeons in the development of new valve, ventricular assist, lung volume reduction, and other technology (3-F Therapeutics, Thoratec, Spiration). We have dynamic leadership in our major surgical societies that are involved in all aspects of the clinical, academic, educational, administrative, and political arenas. We are also seeing the unrealistic expectations and favorable early published results of percutaneous technologies coming back down to statistical reality. The almost biologically unbelievable clinical results with drug eluting stents might not be as wonderful as initially reported, and in fact, may be even more dangerous long term than coronary bypass surgery. Hopefully such emerging data will allow better comparison with outstanding long term historical surgical controls. The pendulum is swinging again... and now back towards us.

Cardiothoracic surgery is special. We do procedures and have responsibility that no other physicians are given the opportunity to have, we take care of some of the sickest patients but we effect some of the most dramatic favorable outcomes. We truly make differences in peoples lives, and the members of this exclusive "fraternity" are remarkable people and enduring friends. Cardiothoracic surgeons are leaders and they will assure a bright and enduring future for this specialty.

- Edward D. Verrier M.D.

CIMS Cardiac Surgery Team

 Dr. Manan Desai
 Dr. Dhiren Shah
 Dr. Dhaval Naik

 +91-96385 96669
 +91-98255 75933
 +91-90991 11133

CIMS Cardiac Anaesthetists Team

Dr. Chintan Sheth | Dr. Niren Bhavsar | Dr. Hiren Dholakia +91-91732 04454 | +91-98795 71917 | +91-95863 75818

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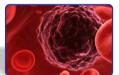
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Ph. : +91-79-2771 2771-75 (5 lines) Fax: +91-79-2771 2770.

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