

Highlights from ICI-Innovations in Cardiovascular Interventions December 3-5, 2007, Tel Aviv, Israel

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Overview

Innovations in Cardiovascular Interventions 2007, www.congress.co.il/ici2008, held in Tel Aviv, Israel focused on new frontiers in interventional cardiology, while at the same time, providing up-to-date reviews of current therapeutics in this fascinating and fast moving field. The meeting is a melting pot of interventional cardiologists, scientists, engineers and entrepreneurs, including the première leaders in this field. The pathway to innovation and device development was discussed and confronted with a resounding march of presentations from young start-up companies that will shape the landscape in the catheterisation laboratory of coming years.

The opening session featured presentations reviewing the impact of innovation on interventional cardiology. The development of this field since the early days of Andreas Gruentzig's first balloon angiography, through balloon and atherectomy technology, metal stents, drug eluting stents (DES) – culminating with the fascinating subject of percutaneous valves – was presented. A view from the Silicon Valley – a small community in global concepts that has impacted the world with its innovative ideas – on the fascinating route from concept to bedside, was discussed. Clearly, this field has not reached a steady-state, typical of maturity. On our way to a less invasive world, new device developments for the treatment of much more challenging scenarios, such as percutaneous valves, correction of valvular leaks, therapies for heart failure, cell therapy and vascular therapies to prevent and treat strokes, are rapidly evolving.

A major topic in today's world is the relationship between academia, clinical practice and the industry in device development and clinical research. The academia/industry role in innovations, mechanisms

to report conflict of interest of physicians and scientists, the long regulatory pathway associated with innovation were highlighted throughout the meeting in various sessions. New challenges transform the world into one big laboratory, a laboratory that has to function in a coordinated fashion in order to match the rapid pace of medical development, yet at the same time comply with the vast variations in availability worldwide.

Technology Parade

A major highlight of the meeting was the Technology Parade, a fascinating sequence of short and structured presentations of new technologies developed by innovative companies and scientists. With the globalisation of clinical research as a major goal to be accomplished, the lectures dealt with pathways to the commercialising of ideas and bridging the gap between clinical innovations, capital and industry.

Presentations in the Technology Parade spanned various areas, including noninvasive diagnosis and imaging, new devices for coronary interventions, navigation and image guided interventions, heart failure and cardiac regeneration, prevention of cardio-embolic strokes, neuroprotection and various other topics (see Table 1).

The Technology Parade sessions provided a quick, colourful and fascinating window into innovations at a very early stage of development with a "glimpse" into the potential future landscape of our catheterisation laboratories. The strength of that session is that beyond understanding the potential changes that may become the clinical tools of our future, physicians are exposed to potential studies that they may want to participate in, young companies have the opportunity to expose their technology at a very early stage and

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Technology Parade

I - DIAGNOSTIC & NAVIGATION

Amos Katz (CardioMeter Ltd)

A Novel Non-invasive Digital Arterial Pulse Wave Analysis during Deep Breathing as an Indicator of Significant Coronary Artery Disease – A Two Centre Study

Daniel Burkhoff (Cheetah Medical, Inc)

Bioreactance Based Noninvasive Cardiac Output Measurement

Moshe Flugelman (MediGuide)

MediGuide's MPS™ Integrated Navigation within the Cathlab

Ran Kornowski (Paieon Medical Ltd)

Integrating Paieon's Coronary Imaging into Diagnostic and Interventional Procedures

Ariel Roguin (Shina Systems)

Integration of Cardiac CT into Coronary Angiography

Chaim Lotan (Arineta Ltd)

The Arineta Cardiovascular Designated CT Scanner

Tamar Gaspar

Fully Automatic Analysis of Coronary CT Angiography (RCADIA Medical Imaging Ltd)

Ran Bronstein, Inbal Mazor

(Symbionix Corp) Patient Based Simulation – Procedure Rehearsal

Peter J Fitzgerald (Corindus Inc)

The Corindus CorPath™ Robotic System for PCI

II - ENDOVASCULAR THERAPEUTICS

David Meerkin (Y-Med Solutions)

YMed – Coronary Bifurcations & Peripheral Artery Disease Solutions

David Baruch (PlaqMed Ltd)

PlaqMed's Sealing Membrane for the Treatment of Vulnerable Plaques

Chaim Lotan (TriReme Medical Inc)

TriReme Medical Inc Bifurcation Stent – Early Clinical Results

Keyur Parikh (OVALUM Ltd)

New Frontiers in Chronic Total Occlusions: CiTop™ guidewire

Chaim Lotan (Inspire-MD)

The MGuard™ – Net Protective Stent to Prevent Embolisation

Ronald Jay Solar (ThermopeutiX, Inc)

Neuroprotection by a New Catheter Technique for Rapid Selective Cerebral Hypothermia

Refat Jabara (Bioabsorbable Therapeutics, Inc)

A Novel Anti-inflammatory Salicylate-Based Bioabsorbable Polymer for Use in Fully Biodegradable Coronary Stents

Silvia Stolarski (ITGI Medical)

Advantages of Using Heterologous Tissue Covered Stents in Saphenous Vein Grafts

III - CARDIAC FUNCTION AND MISCELLANEOUS

Chaim Lotan (Israel)

Hadassah Cardiovascular Innovation Centre (HCIC)

Benny Rousso (Impulse Dynamics)

An Innovative Device Therapy for Heart Failure - Cardiac Contractility Modulation

Gil Hakim (Medispec Ltd)

Extracorporeal Myocardial Revascularisation Therapy (ESMR) to Induce Local Angiogenesis to Myocardial Ischemic Areas Using Low Intensity Focused Shockwaves

Mike Minogue (Abiomed, Inc)

What is New in Circulatory Support Devices with Emphasis on Impella

Tamir Ben-David (BioControl Medical (BCM) Ltd) CardioFit Neurostimulator for Treatment of Heart Failure

Teddy Weiss (Mego-Afek) Computerised Gradual Angioplasty Improves Outcome of Coronary Stenting – Final Results of a Randomised Controlled Trial

Dov Shimon (SMT Research & Development Ltd) AEPD Status Report – Transcatheter Treatment for Prevention of Cardioembolic Stroke

Amir Elami (CorAssist Cardiovascular)

In vivo Safety and in vitro Model Assessment of a New Device-based Approach for Treating Diastolic Heart Failure

Yael Cohen (Gamida Cell) Development of CardioCure™, Ex vivo Expanded Autologous Bone Marrow, to Improve Cardiac Regeneration in Patients Post Acute Myocardial Infarction

interest at the same time to the clinical and the industrial-financial communities including major companies and funds – they thus are exposed to a whole gamut of funding opportunities. Beyond a doubt, this unique “Parade” led to new funding contracts, new research protocols and enhanced the international collaboration that is so important for globalisation.

Next generation drug eluting and bioactive stents

The field of stenting – including bare metal, drug eluting and absorbable stents – was covered in several sessions. New generation bare metal stents with unique surface properties, bioabsorbable stents and drug eluting stents were extensively discussed. Some topics under discussion included: the long term

safety of drug eluting stents, surface coating to safely optimise restenosis, the decision process in choosing among the certified DES, and more. Reviews illuminated the current knowledge about DES and the associated pathologies that may be so important in shaping the long-term clinical response and safety. A consensus has emerged that while there are concerns about an increased risk of late thrombosis, that this is, on the average, a fraction of a percent per year, thus DES are safe and effective if properly used. Due to the recent concern regarding DES safety, a revival of absorbable stents research is apparent. A long line of absorbable stents based on polymer and metal technologies were presented and may shape our armamentarium in combating vascular stenosis in the future.

Complex coronary lesions and vascular interventions

Many challenges continue to feed the creative mind of clinicians and device innovators. Current and new approaches to bifurcation stenting and a review of the new devices that provide safe and reliable access to side branches at a bifurcation location were presented. Coronary interventions in vein grafts and new concepts for safely crossing chronic total occlusions were discussed. New atherectomy devices, femoral artery closure technologies and novel solutions for embolic protection were discussed as well.

Carotid stenting is still at the centre of interdisciplinary debate with diverse views about the role of carotid stenting with respect to endarterectomy. This was brought to this meeting in specific overviews and focused discussions. There is a slow progress in this field, but not at the pace we originally anticipated. It may be that the time will be ripe for larger expansion of carotid stenting only when intracranial interventions start to make an impact on stroke management. Here, cardiologists and vascular interventionalists find a rocky pathway without the full collaboration of neurologists, neuroradiologists and vascular surgeons.

Valvular interventions and structural heart disease

There were several fascinating sessions on this rapidly progressing field. The imagination and innovation involved in developing new therapies and devices are exemplary.

Percutaneous valve intervention that was introduced over twenty-five years ago paved the way to the novel devices that we are seeing today. Percutaneous aortic valve replacement is at its first steps in the clinical market. Will it be accepted? Will the real-life data be better than the initial controlled registries? Will the device be safe in the hands of an expanded circle of clinicians? Mitral valve image guided technologies for percutaneous repair of mitral regurgitation using novel navigational techniques and new devices was another topic of the highest interest. We will have to wait for the next meeting to see more progress here.

Clearly, innovation is making a major impact here. It may revolutionise clinical practice worldwide similar to what has happened with coronary stenting. However, a fascinating aspect in the field of medical innovation is the unknown factors that determine whether a new technology will become robust and widely available to all.

Heart failure and cell therapy

Clearly, there is a large circle of patients with heart failure that need better therapies. Ventricular assist devices and the concept of moving from “bridge to transplant” into “destination therapy” is with us for yet a couple of years more, but it is clear that this field needs a major paradigm shift in order to become of value to a wider circle of patients in need. Cardiac Contractility Modulation (CCM) therapy through electrical stimulation is another technology with promise. Dual-chamber pacing has clearly had its impact on the treatment of heart failure. Telemonitoring of intra-cavity pressures are novel ideas that may change the horizon in upcoming years. This is particularly true for a world that is capable to connect wirelessly to every device and to an implanted chip, which in itself may have an intelligence of

its own. Closing the loop and connecting the pressure chip to an implanted drug reservoir can modulate the blood pressure through the use of this high-tech mechanism.

Cell therapy for myocardial diseases is still seeking an impact. While successes have been recorded in some of the clinical cell therapy programs, this field is still struggling to define the most appropriate methods of delivery and to clinically evaluate the benefit in these complex patients, where the placebo effect and bias are markedly exaggerated by the height of expectations. A fascinating overview of myocardial regeneration, using human embryonic stem cells, included the development of this technology in bench and animal experiments. The use of angiogenic peptides to alleviate ischaemia in patients at end-stage ischaemic heart disease is an established idea that continues to progress.

In summary, novel devices to assist the heart, methods to modify contractility and concepts of cell therapy and tissue engineering are the current basis for future developments in this field.

Imaging before and during catheterisation

Imaging has been a key element in our success in interventions. The cardiac multi-detector CT continues to surprise us with its steep advancement curve, and yet, the indications for its use are under constant debate and public discussions. An all-comers approach to the use of this technology in low-risk patients showed that some 10% of these patients will be detected with significant coronary lesions. X-rays joined with MRI to guide cardiovascular interventions in 3-D, image-guided complex valvular and heart failure interventions and magnetic navigation for cardiovascular interventions were some other novel ideas brought to the discussion table. A new concept of hybrid CT-angiography image registration to provide an accurate 3D course of the arterial segment may become one of our navigation tools in tomorrow's catheterisation laboratories. Creating the right environment for hybrid procedures between surgical and percutaneous interventions critically depends on a combination of powerful imaging tools in the operation suite. Such procedures may be aortic valve replacement by percutaneous or trans-apical approaches, hybrid revascularisation and a combined surgical-percutaneous approach to treat atrial fibrillation.

From concept to regulatory approval

A new technology, including the in vitro results from bench-top tests, was presented to an audience of physicians, entrepreneurs and industry. What are the most efficient steps to regulatory approval? International industry and academic leaders came together to present their views on the required animal models and pre-clinical studies, the approaches to clinical trials and its design as well as the most appropriate steps and approaches towards an IDE application. It was a fascinating brainstorming session for all the disciplines involved.

The meeting was a true march of innovating technologies, current and future clinical practice and a fascinating world of interactions between clinicians, industry, financial venues and academia. This unique setting will go on annually, as a focus and highly concentrated melting pot between medicine, academia and industry for the advancement of cardiovascular care through innovations.