



# SOLACI DAILY

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The Official Newspaper of SOLACI Congress

## Welcome to SOLACI '10

XVI SOLACI Congress / XX CACI Congress

By Dr. Oscar Mendiz, MD

Dear colleagues and friends,  
On behalf of the Organizing Committee, it is my pleasure to welcome you to this SOLACI–CACI 2010 congress in Buenos Aires.

The Latin American Society of Interventional Cardiology (SOLACI) and the Argentinean College of Interventional Cardioangiologists (CACI) have granted me the honor of being President of SOLACI 2010 and it has been my privilege to work with a team made up of a great number of distinguished colleagues who deserve my gratitude for their cooperation, ideas, suggestions, personal support and friendship.

This SOLACI meeting aims to review the breakthroughs of interventional procedures within the scope of the Latin American reality, as well as the experiences and opinions of local experts.

Our Scientific Committee has prepared an exciting program which will cover almost the entire spectrum of cardiovascular and vascular interventions with the state-of-the-art practices,

within the frame of an active interaction with clinical cardiologists and vascular surgeons.

We are pleased to have a high number of distinguished faculty members from LATAM and around the world. We will not only welcome most of the top key-opinion leaders in interventional cardiology but also other well known specialists who will present a comprehensive review of the current practice and latest advances.

I am proud to say that the interest in showcasing research at SOLACI meetings has been steadily growing over the past few years, and this situation is reflected in the record number of high-quality abstracts submitted from almost all participating countries. Some of these abstracts have been submitted for fast-

(Cont. Page 3)



Dr. Oscar Mendiz

## Bienvenido a SOLACI '10

XVI Congreso SOLACI / XX Congreso CACI

Por Dr. Oscar Mendiz

Estimados colegas y amigos:

En nombre del Comité Organizador, me complace darles la bienvenida a este Congreso SOLACI–CACI 2010 en Buenos Aires. La Sociedad Latinoamericana de Cardiología Intervencionista (SOLACI) y el Colegio Argentino de Cardioangiólogos Intervencionistas (CACI) me han conferido el honor de ser el Presidente de SOLACI 2010 y ha sido un privilegio para mí trabajar con un equipo conformado por una gran cantidad de colegas destacados que merecen mi más sincero agradecimiento por su cooperación, ideas, sugerencias, apoyo personal y amistad.

Nuestro Comité Científico ha preparado un programa muy interesante que cubrirá casi todo el espectro de las intervenciones cardiovasculares y vasculares con prácticas de avanzada, dentro del contexto de una interacción activa con cardiólogos clínicos y cirujanos vasculares.

Nos complace contar con una gran cantidad de distinguidos miembros invitados de Latinoamérica y del mundo. No sólo recibiremos a los líderes de opinión más importantes de la cardiología intervencionista, sino también a otros especialistas reconocidos que presentarán un repaso integral de la práctica actual y de los últimos avances.

Esta reunión de SOLACI tiene como objetivo repasar los avances más importantes de los procedimientos intervencionistas en el contexto de la realidad latinoamericana, así como las experiencias y las opiniones de los expertos locales.

Nos complace contar con una gran cantidad de distinguidos miembros invitados de Latinoamérica y del mundo. No sólo recibiremos a los líderes de opinión más importantes de la cardiología intervencionista, sino también a otros especialistas reconocidos que presentarán un repaso integral de la práctica actual y de los últimos avances.

Me enorgullece informar que el interés por presentar las investigaciones en las reuniones de SOLACI ha crecido en forma constante durante los últimos años, y esta situación se ve reflejada en la cantidad récord de temas (Cont. Pag. 3)

## Radioprotection

What Do We Need to Know and How to Protect Ourselves

By Ariel Durán, MD

According to figures of the International Atomic Energy Agency (IAEA), the annual number of diagnostic X-rays exposures is 2,5 billion and the number of therapeutic exposures 5,5 million; 78% of them account for medical applications, 21% for applications in odontology and 1% for techniques associated with nuclear medicine.

Registro SOLACI's data show that between 1998 and 2005, 1,770,977 procedures were reported in Latin America; 446,999 (25.2%) of them were of therapeutic nature. This results in an annual average of more than 221,372 procedures per year in 19 countries in Latin America, which

translates into a mean of 341 diagnostic catheterizations per million of inhabitants and per year (2).

These figures reveal the importance of X-rays as a diagnostic and therapeutic tool, but because of its potential for producing side effects, both in patients and in occupationally exposed staff, it is our duty to become familiar with certain protective measures that may help us reduce the risks.

Additionally, the progressive development of our specialty has increased the risk since there are increasingly complex procedures that were not performed before and that involve longer radiology times: multiarterial cases, brachytherapy, percutaneous aortic... (Cont. Page 5)

## Abstract Submission Record

By SOLACI Committee

Original papers play a key role in scientific meetings because they reflect the real basic and clinical research submitted to the events. High quality abstract submissions are crucial to evaluate the scientific content of the congress and abstract presentations are considered a unique opportunity for close interaction between colleagues involved in research.

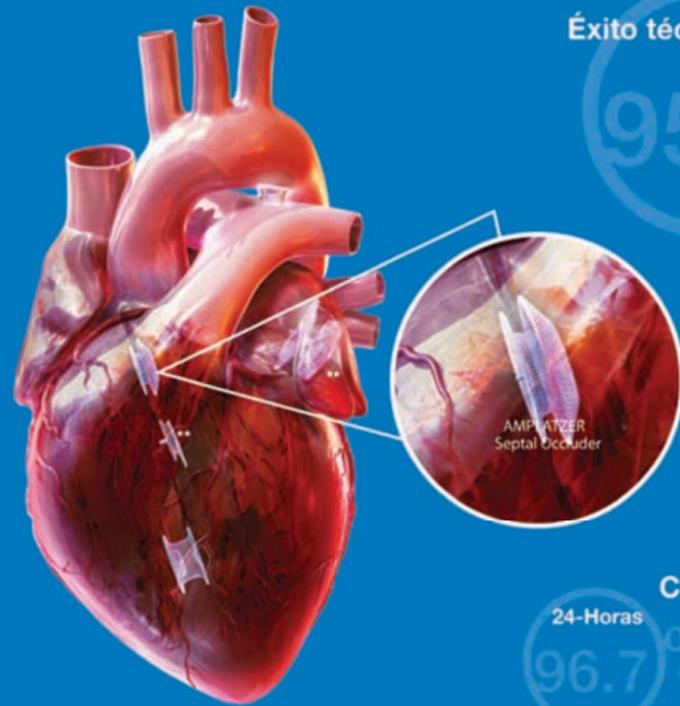
The number of abstracts submitted to the different SOLACI congresses has been steadily growing and this year we received over three hundred and sixty presentations, not only from Latin America but also North America, Europe, the Middle East and Asia, thus underlining the expanding research in the region and

an increasing interest in this meeting.

Moreover, the announcement of the "best abstracts competition" for fast-track review at the prestigious EuroIntervention Journal has undoubtedly had a positive role in this situation. The best six abstracts selected by Prof. Patrick Serruys -EuroIntervention's Editor in Chief- were sent for peer review analysis and some of them will be published in the journal. We feel that maintaining this activity in future SOLACI meetings will be a stimulus for researchers from Latin America and rest of the world to present at SOLACI the results of their work.

All approved abstracts have been published in Vol. 1 number 2 of the Revista Argentina de Cardioangiología Intervencionista and will be distributed for free among all those attending to the meeting. (Cont. Page 3)

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SOLACI DAILY  
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Wednesday, 11th August, 2010

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(Cont. of "Welcome to Solaci 2010")

...-track review and, if accepted, they will be published in the EuroIntervention Journal. Our audience will also have the opportunity to read all submitted abstracts in the Revista Argentina de Cardioangiología Intervencionista. We have prepared 25 high definition live cases which are going to be broadcasted from four centers in Buenos Aires with guest experts and operators. During these live sessions we will try to cover different techniques and approaches for complex adult and pediatric cases. I would also like to extend my warmest welcome to those colleagues who belong to other disciplines of cardiovascular and vascular medicine. One of the main objectives of this meeting is to interact and learn from each other about the most effective clinical approaches to most prevalent cardiovascular disease.

And of course, we welcome a great number of nurses and technicians who not only have a very attractive program for their own sessions but also a high interest to participate in the general sessions. They are an important part of the interventional team and should be informed and trained.

Today, after the opening lecture and ceremony, we will have the traditional "cocktail reception" in the exhibit area.

Regarding the new activities, I would like to invite you all to the evening symposia, where you can "learn and dine". It will take place tomorrow at 6.30 p.m. in the 2° underground floor of the Hilton Hotel and will finish early enough for those who still have the energy to enjoy the entertaining nightlife of Buenos Aires, the city that never sleeps.

Big international meetings have an official newspaper where all the activities of the meeting are reflected as well as other relevant information, which is not only brought to attendees but also to other people who will read it once the event is over. With this in mind, we are pleased to introduce this year the SOLACI DAILY, the official SOLACI Congress newspaper. This is our first experience with a publication of this kind; it is very challenging and time consuming and therefore I would like to thank Dr. José Alvarez for accepting to coordinate the editorial team and everybody who has cooperated with articles and interviews.

I want to apologize for all the mistakes and all those little things that you might not like or that you think we should improve or do in a different way; in this regard, I would like to ask for your cooperation: please help us improve the quality of our events by sending your feedback and suggestions to our Congress Office (congreso@solaci.org).

Although the global economy is not doing that well, and many companies have suffered a huge impact in their budget after the recent crisis, I am happy to confirm that over fifty of them strongly believe in our mission and objective. This has been clearly demonstrated with their tremendous effort to participate and their unrestricted grant support. Finally, we look forward to welcoming you to SOLACI 2010 and hope that at the end of the meeting your enthusiasm to attend will have been compensated with a very pleasant and teaching experience.

Oscar Mendiz, MD  
President, SOLACI - CACI Congress 2010

(Cont. of "Bienvenido a Solaci 2010")

...libres de excelente calidad que hemos recibido de casi todos los países participantes. Algunos de éstos han sido enviados para una rápida revisión y, en caso de ser aceptados, serán publicados en la revista EuroIntervention Journal. Nuestra audiencia también tendrá la oportunidad de leer todos los temas libres enviados en la Revista Argentina de Cardioangiología Intervencionista. Hemos preparado 25 casos en vivo de alta definición que serán transmitidos desde nuestros centros de Buenos Aires con expertos y operadores invitados. Durante estas sesiones en vivo intentaremos cubrir diferentes técnicas y enfoques para casos complejos en adultos y pediátricos.

También deseo extender mi más cálida bienvenida a todos los colegas que pertenecen a otras disciplinas de la medicina cardiovascular y vascular. Uno de los principales objetivos de esta reunión es interactuar y aprender unos de otros acerca de los enfoques clínicos más eficaces para las enfermedades cardiovasculares más frecuentes. Y, por supuesto, damos la bienvenida a una gran cantidad de enfermeros y tecnólogos que no sólo cuentan con un programa muy atractivo para sus propias sesiones, sino que están muy interesados en participar en las sesiones generales. Ellos constituyen una parte importante del equipo intervencionista y, por lo tanto, deben estar informados y capacitados. Hoy, después del discurso y de la ceremonia de apertura, realizaremos el tradicional "Cóctel de bienvenida" en el área de exhibiciones.

En relación con las nuevas actividades, los invito a todos ustedes a los simposios vespertinos, donde pueden "aprender y cenar". Éstos se llevarán a cabo mañana a las 18.30, en el 2° subsuelo del Hotel Hilton y finalizarán lo suficientemente temprano para aquellos que aún tengan energías para disfrutar de la entretenida

da noche de Buenos Aires, la ciudad que nunca duerme. Las grandes reuniones internacionales cuentan con un diario oficial en el que se reflejan todas las actividades de la reunión, así como otra información relevante, que no sólo se hace llegar a los asistentes, sino también a otros que lo leerán una vez que finalice el evento. Con esto en mente, nos complace presentar este año el SOLACI DAILY, el diario oficial del Congreso SOLACI. Ésta es nuestra primera experiencia con una publicación de este tipo; es un gran desafío y exige mucha dedicación y, por lo tanto, deseo expresar mi agradecimiento al Dr. José Alvarez por aceptar coordinar el equipo editorial y a todos aquellos que han colaborado con artículos y las entrevistas.

Pido disculpas por todos los errores y las pequeñas cosas que puedan disgustarles o que consideren que debemos mejorar o hacer de manera diferente; en este aspecto, me gustaría solicitar su cooperación: ayudennos a mejorar la calidad de nuestros eventos enviando sus comentarios y sugerencias a nuestra Oficina de Congresos (congreso@solaci.org).

Aunque la situación de la economía mundial no es la mejor y muchas compañías han sufrido un gran impacto en su presupuesto después de la reciente crisis, me complace confirmar que más de cincuenta de ellas creen verdaderamente en nuestra misión y objetivo. Esto lo han demostrado con claridad con el enorme esfuerzo que han hecho por participar y con el otorgamiento de subsidios ilimitados.

Por último, esperamos con ansias darles la bienvenida a SOLACI 2010 y es nuestro sincero deseo que al final de la reunión su entusiasmo por asistir se vea recompensado con una experiencia placentera y enriquecedora.

Dr. Oscar Mendiz  
Presidente, Congreso SOLACI-CACI 2010

(Cont. of "Abstract Submission Record")

It is worth mentioning that not only the quantity but also the quality of research submitted is improving and we hope that this situation will remain in upcoming meetings. We received basic and clinical research, retrospective and prospective, unique and multi-center trials.

As an obvious consequence, a greater number and better quality could intimidate and thus prevent some local investigators from sending their papers, but, on the opposing, we hope that this situation will induce a positive stimulus for more and better abstracts submissions from LATAM and around the world. Nurses and Technicians have also an interesting participation and we encourage them to increase their submissions by sending their own papers. Finally, I strongly recommend not only attending oral abstracts presentation sessions but also those dedicated to poster presentations. Due to the great number of abstracts submitted, you will find excellent papers presented for discussion and this is one of the most important educational activities in the congress.

## Wednesday Schedule 11/08

Wednesday August 11th	01 Pacific	02 Atlantic	03. Buenos Aires A-B	05. Buenos Aires C Nurses & Technicians	06. Pacific	07. Taiwan
08:00 - 08:30	Welcome Message					
08:30 - 10:30	Live Cases	Images in Interventional Cardiology I	Vascular Interventions	Epidemic control in ICU/CCU and the Cathlab. Neurointerventions		
10:30 - 12:00	Live Cases	Images in Interventional Cardiology II	Abstracts Session I	Interventional Radiology	Ultimate Technology Symposium (Sponsored By SOLACI)	From Basic to Clinical Research
12:00 - 13:30	Sirelinus: From Transforming Efficacy with Cypher to Advanced Safety with NEVO (Lunch Symposium Cordis)	Late Breaking Technologies (Lunch Symposium Medard-Possis)	The Drug-Cluting Balloon (DOR: Next Perspectives)(Lunch Symposium EuroCo)			
14:00 - 15:30	EuroPCR@SOLACI Live & Live in Box Cases	Interventions for Clinical Cardiologists I	Therapeutic Alternatives for the Prevention of Coronary Restenosis	Structural Diseases	Transradial Intervention: Why and How Do We Go to TRI? (Workshop sponsored by Terumo)	
15:30 - 17:00		SAC FAC & Spanish Society of Cardiology @ SOLACI	Limb Salvage	Our Role	Radiological Protection for Interventional Cardiologists	
17:00 - 18:00	Live Cases			Management: An Alternative Role		
18:00 - 19:30	Opening Lecture (G Stone: TITULO de la conferencia) & Ceremony					

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(Cont. of "Radioprotection")

...valve implantation, mitral valve devices, prosthesis implantation in thoracic or abdominal aorta, etc.

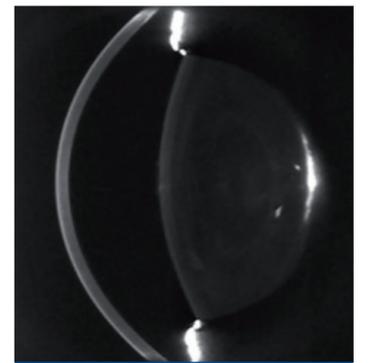
X-rays can cause 2 types of harmful effects: stochastic or probabilistic, which are basically the induction of cancer, and deterministic, which are lesions in the skin, crystalline lens, or in other exposed organs. The former do not depend on the dose received while the latter are directly related to the dose (duration of the procedure, type of fluoroscopy, arc angle, etc). These effects affect patients as well as main operators or room staff, therefore, recommendations will vary if they are for one or the others.

Regarding patients, the ideal situation is to set the table as high as possible since this moves the chest away from the radiation beam and, at the same time, to vary (whenever possible) the angulation of the arc so as not to concentrate on the same area of the skin. Also, we must film as little as possible since during this instance the dose multiplies by 10 or 20. Additionally, we must remember that extremely angular projections must go through a larger body section, which also increases the dose considerably. We must remember to collimate and place semi-transparent filters correctly so that "the image becomes more homogeneous", which results not only in a better image quality but also in a reduction of the radiation that is received.

In terms of recommendations for operators, we



Radioinduced crystalline lens opacity observed by using the "retroillumination" technique.



Posterior subcapsular crystalline lens radioinduced opacity.

are in a win-win situation, which means that everything we have said for patients reduces the occupational dose for both physicians and room staff. There are, however, other recommendations that we will mention, which are exclusively aimed at improving the occupational dose. It is recommended that you never expose your hands to the x-rays beam, and also remember that radiation decreases with the square of the distance from the tube, which means that if we can double (at least instantaneously or, for example, when filming) our distance to the tube, the radiation we receive decreases to 25%. Use all the radioprotection items available,

and if they are not available, make every effort to get them. Whenever you are inside the room use a lead-apron, preferably, of the wrap around type and in two pieces so as to balance the weight. Today, there are new materials in the market which are lighter than lead. Always use lead glasses. Remember that interventional cardiologists have considerably more opacities than the rest of physicians and, therefore, we are carrying out within the framework of this Congress a new phase of the Retrospective Evaluation of Lens Injuries and Dose (RELID) study, in which a distinguished group of ophthalmologists will perform the necessary evaluation so

### THEATRE PACARA

Hour: 15:30 – 17:00

Retrospective Evaluation of Lens Injuries and Dose (RELID STUDY)

that you know whether you have opacities or not. This exam is recommended for interventional cardiologists as well as for room staff.

Always use your thyroid protector and room accessories protectors. Always work behind a lead-screen and of the skirt adhered to the examination table.

Always use your personal dosimeter and pay attention to its measurements.

## Percutaneous Occlusion of the Left Atrial Appendage with Amplatzer Cardiac Plug (ACP)

By Armando Bethencourt, MD. \*

**A**trial Fibrillation (AF) is the most common arrhythmia in clinical practice, especially in the elderly. One of the most frequent complications of AF is the cardioembolic Cerebrovascular Accident (CVA) (15-25%). Most of the clots that may embolize are formed in the Left Atrial Appendage (LAA), up to 90% in non-valvular AF. Patients at higher risk of suffering a cardioembolic CVA are those with heart failure, hypertension, aged 75 and older, diabetes and/or with previous CVA (CHADS2 score). Permanent Oral Anticoagulant Therapy (OAT) is the recommended treatment for patients with non-valvular AF and CHADS2 score. In clinical practice, however, only 1/3 of patients with permanent AF receive AOT for several reasons. Percutaneous occlusion of LAA is presented as an alternative to AOT, especially in high cardioembolic risk patients for whom AOT is not possible or undesired.

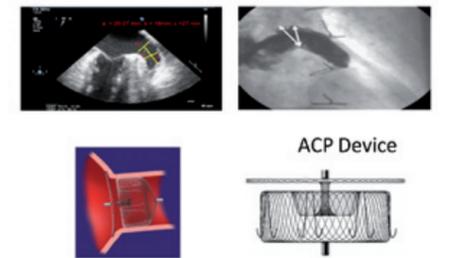
The results of the first randomized clinical trial of AOT vs. Percutaneous Occlusion of LAA with the Watchman device (Holmes DR et al, Lancet 2009;374:534-42) have been recently published, and they show its clinical usefulness in reducing short- and mid-term embolic CVA risk.

### LAA Implanted ACP Device



LAA Implanted - ACP Device

### Echographic and Angiographic Anatomy of LAA



Echographic and Angiographic Anatomy of LAA - ACP Device

The ACP has been mainly used in Europe in the last year and a half, basically in patients with OAT contraindication and/or with severe hemorrhagic complications derived from OAT treatment. In Argentina and Chile its use started in mid-2009.

The initial European experience, recently released in the EuroPCR held in Paris in May 2010 (Park JW et al, EuroIntervention, Suppl H, H157, May 2010), regarding the collection of pre-registration data, assessed the feasibility and safety at 24 hours after ACP implantation. In 137 of 143 patients on whom LAA occlusion was attempted, the procedure was successfully

in 132 (96.4%). There were severe complications in 10 patients (7.0%): 3 patients, ischemic stroke; 2 patients, device embolization, both recaptured percutaneously; 5 patients, pericardial effusion requiring drainage. Minor complications: 4 cases of irrelevant pericardial effusion, 2 cases of transient myocardial ischemia, 1 case of loss of the device in the peripheral venous system. In the preliminary experience in Spain and Portugal (72 patients, 94.5% implantation success), personal communication A. Bethencourt, MD, embolic clinical events were not reported at initial follow-up (between 7 days and 16 months) of 66 patients.

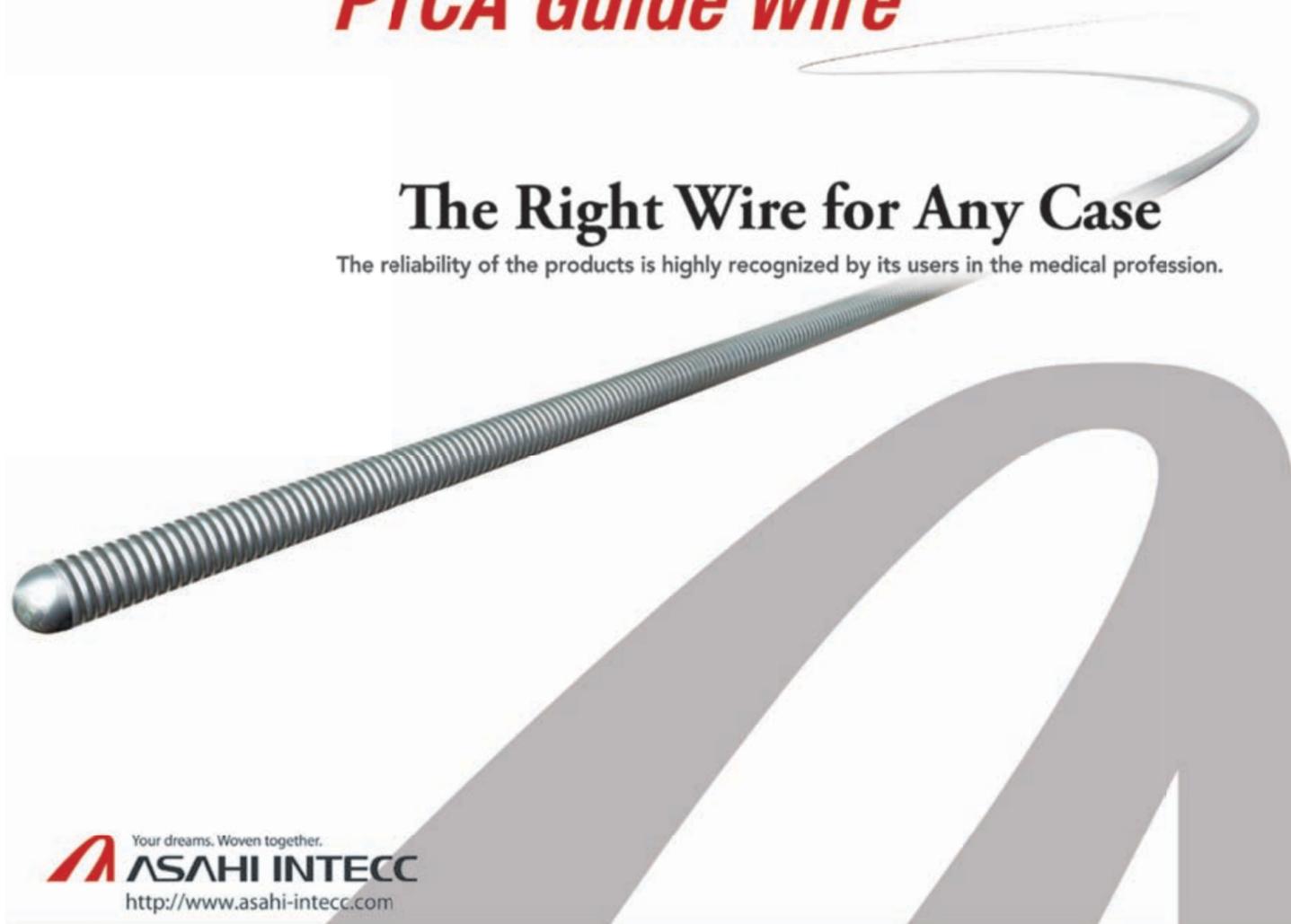
In conclusion, ACP implantation is feasible, it enables percutaneous occlusion of LAA and it is relatively safe. The % of severe complications and the learning curve require restricting its use, in this initial stage, to high risk AF patients with no possible OAT and by expert interventional cardiologists. There is a need for randomized studies with longer term follow-up that help determine if this technique will become an alternative to OAT in most of AF patients.

\* Chief, Cardiology Service. Son Dureta University Hospital. Palma de Mallorca. Balearic Islands. Spain

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## XIII Technical Nurses and Technicians Congress

### Dear colleagues and friends:

Once more the Latin American Society of Interventional Cardiology SOLACI holds its new scientific event for Technical Nurses and Medical Technicians from all around Latin America, the XIII Conference within the context of the XVI SOLACI Medical Congress. We believe that these days of scientific encounter will be held in an environment of fellowship with the possibility of acquiring new knowledge and experience. With this aim, the purpose of both Committees is to invite you to actively participate in all the activities we are organizing for all of you.

As Chairman of this Organizing Committee, I would like to express my best wishes hoping that every one of you can actively participate in this unforgettable experience that SOLACI holds every year with the only purpose of becoming "Better Healthcare Professionals." My best wishes for your and I say goodbye looking forward to seeing you again.

**Tec. Rx. Alberto Zichert**  
Chairman of the Organizing Committee

### Dear colleagues and friends:

2010 gathers us again in the SOLACI 2010, XIII Technical Nurses and Technicians Congress, one of the most important scientific meetings in Latin America. The Organizing and Scientific Committees have made a great effort to organize a congress whose scientific content is considered innovative and attractive by all of you. We designed a scientific program based on workshops, round tables, controversies, conferences and case discussions, so as to respond to all of the challenges faced by our speciality in the XXI Century, which allows for the exchange of scientific and professional information among all the areas of knowledge that unite our SOLACI. We will be honored with the presence of

many world-class speakers, both foreign and national, which guarantees the scientific success of the congress. During the congress we can contrast our experiences, opinions, desires and expectations in a few days in which we will share training and entertainment. It is an honor for me to chair this Scientific Committee, and on behalf of all its members I invite you to participate in the SOLACI 2010, XIII Technical Nurses and Technicians Congress. Welcome to our country and to our congress.

**Lic. Alejandro G. Incarbono**  
Chairman of the Scientific Committee

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## Long-term Clinical Results for Medtronic CoreValve System

Broad Clinical Experience with Medtronic CoreValve Transcatheter Aortic Valve Implantation (TAVI) System: High Procedure Success and Positive Clinical Outcomes Makes TAVI a Viable Treatment Alternative for Symptomatic Aortic Stenosis Patients

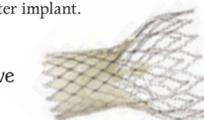
By Thomas Vassiliades

Valvular heart disease importance is increasing as the population ages. The most common symptomatic valvular disorder in the Western world is aortic stenosis (AS), predominantly seen in elderly patients and largely degenerative in etiology. The quality of life and survival with medical management in symptomatic AS is poor, with mortality rates at 1, 5, and 10 years of 38%, 68%, and 82%, respectively. Surgical aortic valve replacement (AVR) has been the gold standard treatment for severe AS, providing symptomatic relief and prolonging life. However, some AS patients are denied surgical AVR due to the presence of significant risk factors such as advanced age, non-cardiac co-morbidities or frailty. Fortunately, transcatheter aortic valve implantation (TAVI) has emerged as a viable alternative for symptomatic AS patients who are denied surgical AVR due to prohibitive operative risk. Approved and available for clinical practice for three years, over 17,000 TAVI implants have been reported worldwide.

The Medtronic CoreValve transcatheter aortic valve system received CE (Conformité Européenne) Mark in 2007. It has been implanted in over 10,000 patients in over 32 countries, and is considered the world's market-leading transcatheter aortic valve when implanted percutaneously. The current CoreValve system includes an 18-French self-expanding bioprosthesis that is typically delivered percutaneously through the femoral artery. It has a unique frame and leaflet design that allows for the treatment of AS in varying patho-anatomy. Clinical data on the longer term efficacy and safety of the CoreValve system were recently presented at EuroPCR. Data presented during the "TAVI Facts, Figures and National Registries" session included findings from registries from Belgium, France, Germany, Italy and the United Kingdom; representing 2,039 CoreValve patients. Overall, the results demonstrated sustained positive outcomes at six months and in some studies, one year after the CoreValve procedure. All registries showed procedure

success rates above 97% and 30-day mortality rates ranging from 5% to 15%. One year survival rates ranged from 79% to 82%, exceeding medical management survival expectations in this population. The Italian Registry had the largest number of CoreValve patients (772) and collected the most comprehensive data. It found that the CoreValve provided highly significant and long-term improvements in symptoms and a reduction in New York Heart Association (NYHA) functional class in the majority of patients: 96% of patients remained in NYHA Class I or II at one year. In addition, all hemodynamic performance indicators improved, and left ventricle hypertrophy decreased after implant.

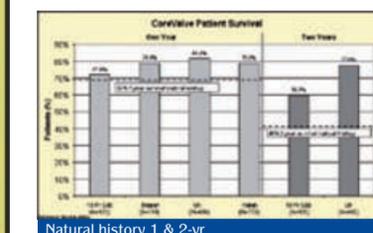
CoreValve



Two-year results from the pivotal 18-French CoreValve multi-center prospective study were also presented at EuroPCR by Professor Ulrich Gerckens.<sup>7</sup> The study evaluated 126 patients at nine centers in Europe and Canada. Positive two-year clinical results were presented, including:

- NYHA functional class status improved at least one classification in 74% of patients.
- Significant valve orifice area improvements were achieved (0.72 cm<sup>2</sup> vs. 1.71 cm<sup>2</sup>, p<0.001).
- Significant peak and mean valve gradient decreases were observed (from 72.5 to 18.6mmHg, and 46.8 to 9.0 mmHg, respectively).
- Left ventricular ejection fraction improvements seen at one year remained stable at the two-year interval (56 %).
- Two-year survival data exceeded that expected for medical management alone: 60% overall survival and 74% cardiac survival

The French study also supported a highly favorable safety profile for the CoreValve system. There were no frame fractures, structural valve deterioration, or valve migration reported over the two-year follow up period. These new results reconfirm findings from previous clinical studies that demonstrated high procedure success rates and positive clinical outcomes for CoreValve patients. To learn more about TAVI and the Medtronic CoreValve system, come to The Future of Interventional Cardiology (Medtronic-sponsored symposium) at 12 noon on August 12 in the Main Arena (SOLACI 2010, Bs. As. Hilton Hotel).



Natural history 1 & 2-yr



## Changing the Standard of Care in STEMI PCI: Combining mechanical reperfusion and pharmacologic therapy to improve myocardial perfusion

By Rajesh M. Dave, MD, FACC, FSCAI\*

Primary percutaneous coronary intervention (PCI) to restore coronary blood flow is the standard of care for ST-elevation myocardial infarction (STEMI) PCI. There are certain parameters utilized for assessment of success in primary PCI which include TIMI flow, myocardial blush grades and ST-segment resolution. A recently published trial, Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS), demonstrated that patients that did not achieve a myocardial blush grade of at least 3, had a 5-fold higher rate of death at 30 days. Even though aspiration catheter thrombectomy is successful in restoring the flow, it is often incomplete in removing the full degree of thrombus. Despite aspiration thrombectomy and use of IV Abciximab in the TAPAS study, only 45% of patients had blush grades of 3. Thiele et al<sup>1</sup> recently published a randomized trial suggesting that the use of intra-coronary (IC) Abciximab is emerging as an important adjunct to the current treatment algorithm for STEMI PCI. Their study concluded that IC Abciximab acts as powerful thrombolytic agent in high concentrations, "which may facilitate the diffusion of the antibody to platelets inside the flow-limiting thrombus, thus resulting in improved dissolution of thrombi and microemboli

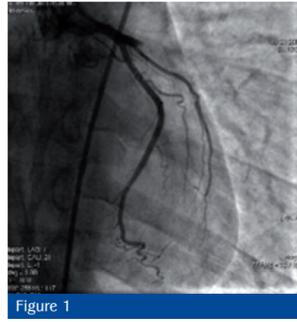


Figure 1

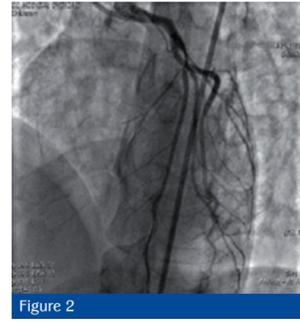


Figure 2

at the ruptured plaque and further downstream in the microcirculation". In this study, patients receiving IC Abciximab had lower infarct size when compared to patients receiving IV Abciximab as measured by MRI. The most contemporary meta-analysis of IC versus IV delivery of Abciximab suggests that STEMI patients have significantly lower mortality, and a trend towards less MACE events. Herein, we propose a new strategy utilizing aspiration/thrombectomy, combined with pharmacologic intervention, which has promising results (improvement in myocardial blush grades and reduction in infarct size) in our practice. In vitro studies have demonstrated that IC glycoprotein IIb/IIIa inhibitors, in high concentration, virtually disaggregate fresh throm-

bus and also enable nonantithrombotic effects such as lytic properties and anti-inflammatory effects to be expressed. IC injection via guide or end hole catheter does attempt to deliver the drug as close to the infarct site as possible. However, this approach has some shortcomings. When a drug is delivered down the guide catheter, it will be diverted through all of the bifurcations before it reaches the culprit lesion. Some drug may reach the target destination and will be certainly in a higher concentration than through IV delivery. However, the drug will quickly be diluted into the bloodstream within a couple of heartbeats and soon reach lower IV concentrations. ClearWay™ Therapeutic infusion balloon (Atrium Medical Corporation, Hudson, NH) is

a low-profile, rapid exchange therapeutic infusion catheter and is indicated for localized perfusion of various diagnostic and therapeutic agents into the coronary and peripheral vasculature. By atraumatically occluding flow, the balloon enables local drug delivery to reach approximately a 500-fold greater drug concentration versus systemic delivery. In addition to IC delivery of Abciximab, we also employ the strategy of either adenosine or sodium nitroprusside delivery via ClearWay prior to stent implantation in STEMI PCI, especially in the presence of high thrombus burden lesions. Case Presentation: 38 year old female presents to the ER with 2 hours of chest pain. During consent, she is cardioverted x3. She was taken emergently to the lab, and placed on a balloon pump. Wire was placed in the lesion, and manual extraction of the LAD was attempted, resulting in embolization of Rhamus and Circumflex. Patient was Cardioverted again. ClearWay was placed in the Left main, and a bolus only administration of Abciximab was delivered, instantly resolving the thrombus burden, saving this patient's life by establishing TIMI-3 flow in the infarct-related artery and resolving slow flow in the Circumflex and Rhamus.

\* Chairman, Endovascular Medicine, Pinnacle Heart and Vascular Institute at Harrisburg Hospital, Harrisburg, Pennsylvania

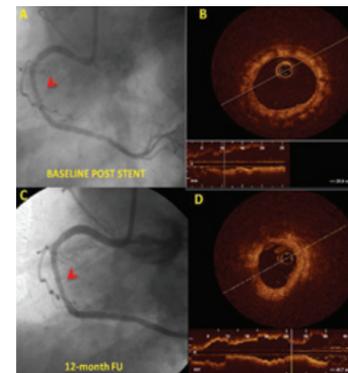
## Optical coherence tomography

Optical coherence tomography (OCT) is a newly developed method of high-resolution intravascular imaging, which, in contrast to intravascular ultrasound, uses infrared light emission instead of sound enabling real time in situ cross-sectional images of tissue without the need to excise and process a specimen as in conventional biopsy and histopathology. It provides a ten-fold higher resolution (10-15 µm) and fewer image artifacts than conventional intravascular ultrasound (IVUS), which has a limited axial resolution of the ultrasound waves (100-150 µm) and the constant presence of artifacts around stent struts (side lobes, shadowing).

By J. Ribamar Costa Jr\*

**Clinical Applications**  
Currently, OCT has been basically used in three different fields of clinical research:  
a) **Characterization of vulnerable plaques** - Its higher definition enables a totally new view of the arterial wall, making possible the in-vivo identification of coronary structures previously only observed in post mortem examination. Among the available imaging modalities in the

clinical scenario, OCT, with its highest resolution is the only modality able to visualize a thin-fibrous cap and measure the thickness of the fibrous cap in the lipid-rich plaque (figure). Furthermore, the quantification of macrophage content within atherosclerotic plaques has been performed experimentally using next-generation OCT equipments.  
b) **Assessment of coronary stent "vulnerability"** - Given its high resolution, OCT can iden-



Serial evaluation by angiography and OCT of a novel biodegradable sirolimus-eluting stent. Panels A and B show the acute result (right after stent deployment). Panels C and D show the angiogram and OCT at one-year follow-up. We can notice by the OCT evaluation that much of the stent has already been absorbed.

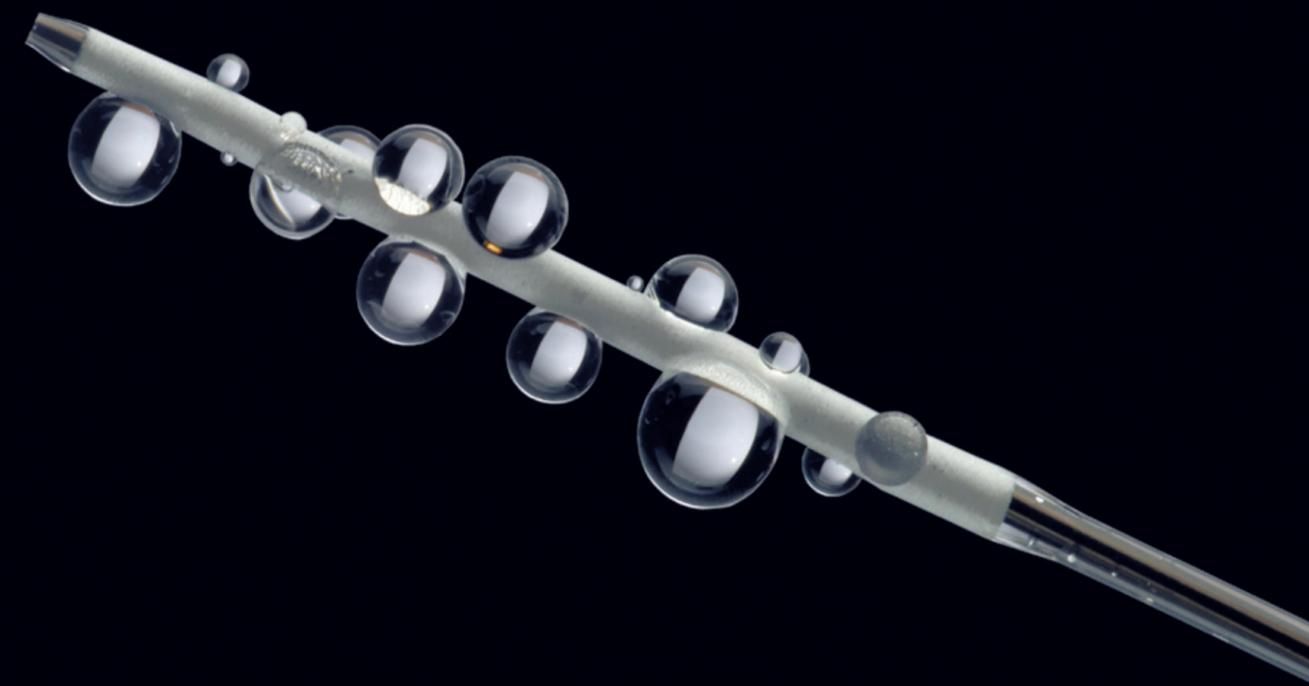
tify even small degrees of neointima formation around stent struts, and also to assess with high accuracy the apposition of stent struts relative to the vessel wall. These issues are of particular importance in the contemporary practice once increased risk of late stent thrombosis has been associated with lack of neointimal coverage of stent struts and with late stent strut malapposition. Late-acquired in-stent apposition has been consistently pointed out as one of the possible

risk factors for stent thrombosis. Some lately published analysis have highlighted the application of OCT for the in vivo detection and comparison of stent tissue coverage at follow-up.  
c) **Assessment of novel devices for intracoronary intervention** - Currently, full bioabsorbable stent technology is under investigation for clinical purpose with the expectation to improve safety of the percutaneous interventional approach. Serial OCT evaluation can also be relevant in assessing novel bioresorbable stents providing precise data about all phase of stent absorption as well as about endothelium modification during the process.<sup>12</sup>

\* Instituto Dante Pazzanese de Cardiologia, São Paulo - Brasil | Instituto de Ensino e Pesquisa do Hospital do Coração - Associação do Sanatório Sírio, São Paulo - Brasil | Cardiovascular Research Center, São Paulo - Brasil

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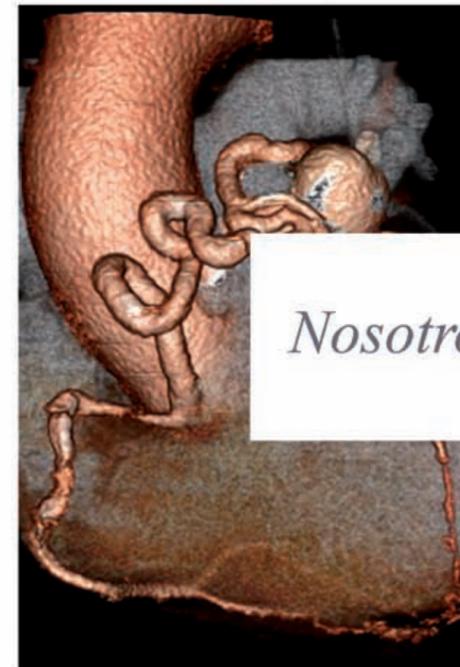
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# Role of Prednisone in the Prevention of Restenosis: From IMPRESS to CEREAS-DES

By Prof. Flavio Ribichini, MD\*

The use of short cycle systemic treatment with prednisone given orally after bare metal stent (BMS) implantation has shown marked efficacy in reducing restenosis in non-diabetic patients with persistent inflammatory state, as indicated by elevated post-procedural C-reactive protein (CRP) levels after stenting. This has been shown in the previous IMPRESS studies that included patients with single vessel disease in a randomized study of oral prednisone versus placebo, and in patients with multi-vessel disease treated with multiple stenting and the same prednisone treatment entered in a prospective registry. Recently, safety and efficacy of this treatment in the two studies at 5 and 8 years follow-up have been reported.

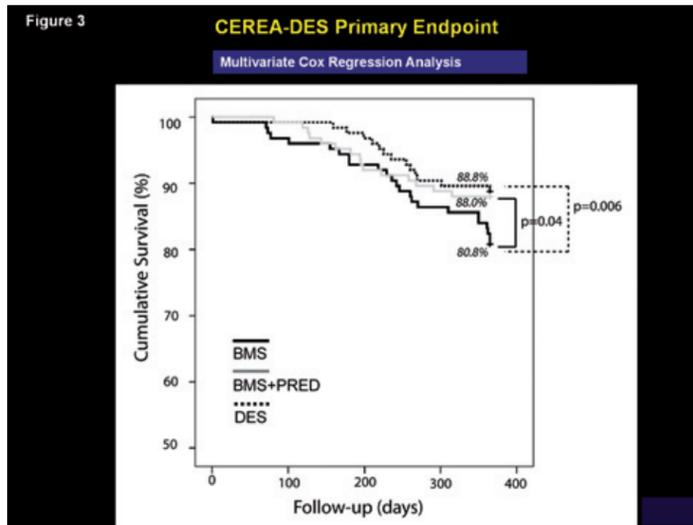
Being inflammation an important component of the restenotic reaction that follows percutaneous coronary interventions (PCI), the use of an anti-inflammatory therapy to prevent restenosis appears as a reasonable intervention. This assumption is supported by experimental data from atherosclerotic animal model that demonstrate the efficacy of the oral prednisone treatment after BMS implantation compared to BMS alone. Indeed, the efficacy of this systemic treatment in reducing neointimal growth after stenting was found to be equivalent to that of the commercially available paclitaxel-eluting stent Taxus Liberté compared to BMS controls. All these preliminary observations have been challenged in the recently concluded multicenter, controlled randomized investigation CEREAS-DES: Cortisone plus BMS or DES versus BMS alone to Eliminate Restenosis Study.

CEREAS-DES is an independent study registered at the Italian Ministry of Public Health as EudraCT 2006-000770-75, and in the US as Clinical Trial NCT00369356. The full protocol of the study is available. The aim of the study is the comparison of the primary endpoint obtained in the control group of patients treated with BMS versus the other two alternative study groups: DES or BMS plus oral prednisone, all assuming a similar optimal adjunctive conventional medical treatment.

The primary endpoint of the study is the survival free of major adverse cardiac events (MACE) at 12 months as analyzed by means of a Cox proportional hazard regression analysis. MACE are: cardiac death, myocardial infarction (MI), either non-Q wave or Q-wave (QWMI), and the need to repeat revascularization (on the same vessel/s treated), i.e. repeated target vessel revascularization (TVR). Prednisone was administered following the treatment scheme used in the IMPRESS studies with slight modifications: 1 mg/kg for the first 15 days; 0.5 mg/kg from day 16 to 30; 0.25 mg/kg from day 31 to 40. The drug was associated to anti-acid therapy during the whole period of steroid treatment, ideally a proton pump inhibitor 20mg twice daily; and 20 to 40 mg/day of oral thiazide to reduce liquid retention and



Prof. Flavio Ribichini



blood pressure and prevent calcium depletion. Treatment with prednisone was started ideally the same day of PCI, early after the procedure and independently of CRP values. One-year follow-up was obtained in all patients. Patients receiving BMS alone as compared to those treated with DES or with prednisone had lower event-free survival; the primary endpoint was 80.8% in controls compared to 88.8% and 88.0% in the DES and BMS+prednisone groups respectively (p=0.006 and p=0.04) (Figure). According to the analysis of the sub-group of patients with normal CRP levels after PCI, it seems that the benefit of prednisone treatment is limited to pa-

tients with high post-procedural CRP levels. Our experience with oral prednisone after PCI with BMS in non diabetic patients suggests that the clinical results of this systemic treatment are superior to BMS alone and similar to that offered by first generation DES. This treatment may be a valid alternative in patients that, for various reasons, may not benefit from DES implantation.

\* From the Department of Medicine, Division of Cardiology, University of Verona, Italy. Director Laboratory of Interventional Cardiology, Department of Medicine, Università di Verona

## A NEVOlution with RES technology: advancing the safety bar

NEVO RES-I 12-month follow-up shows that NEVO Sirolimus-eluting Coronary Stent has continued to demonstrate excellent safety and efficacy outcomes compared to Taxus Liberté.

No episodes of stent thrombosis have been reported in the NEVO arm, whereas two ST events have been reported through 12 months in patients treated with the Taxus Liberté stent. Additionally, there was no cases of cardiac death or MI for patients receiving NEVO.

While the trial was not powered for clinical endpoints and thus no statistically-significant differences were observed, the rates of death, MI, the need for repeat revascularization, and stent thrombosis numerically fa-

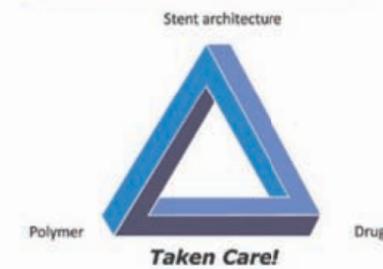
vored NEVO over Taxus Liberté. Similar trends were observed in two subgroups of patients: diabetics and lesion length (≤20mm & >20mm). At the six-month primary endpoint of this prospective, randomized clinical trial, NEVO shows to be statistically superior to Taxus Liberté in in-stent late loss, that was reduced by 64 % in the NEVO arm as compared to the Taxus Liberté arm (0.13 mm compared to 0.36 mm, p<0.001). NEVO was also superior in reducing restenosis. Angiographic restenosis was reduced 86% (1.1 percent in the NEVO arm compared to 7.8 per-

cent in the Taxus Liberté arm, p=0.002). "These data suggest we may be looking at a significant advance in treatment options for coronary disease that allows precise stent-based delivery of drug and is capable of reducing long-term safety complications", said Alexandre Abizaid, MD, the chief of coronary interventions at the Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil. "Since stent thrombosis and the drugs required to protect against it are such significant clinical issues, it is particularly pleasing to see the excellent safety outcomes associated with NEVO™ maintained over 12 months. These results also suggest the need for further study of whether abbreviating or interrupting antiplatelet therapy with this treatment would result in fewer adverse events

than would currently be expected in drug-eluting stent patients". "The additional positive 12-month results from the NEVO RES-I trial are extremely encouraging as they suggest that NEVO could offer improved patient outcomes in the treatment of coronary artery disease", said Campbell Rogers, M.D., Chief Scientific Officer and Global Head, Research and Development, Cordis Corporation. "NEVO is a critical component of our commitment to providing innovative new products, which are transforming expectations for patients and practitioners in the field of interventional cardiology".



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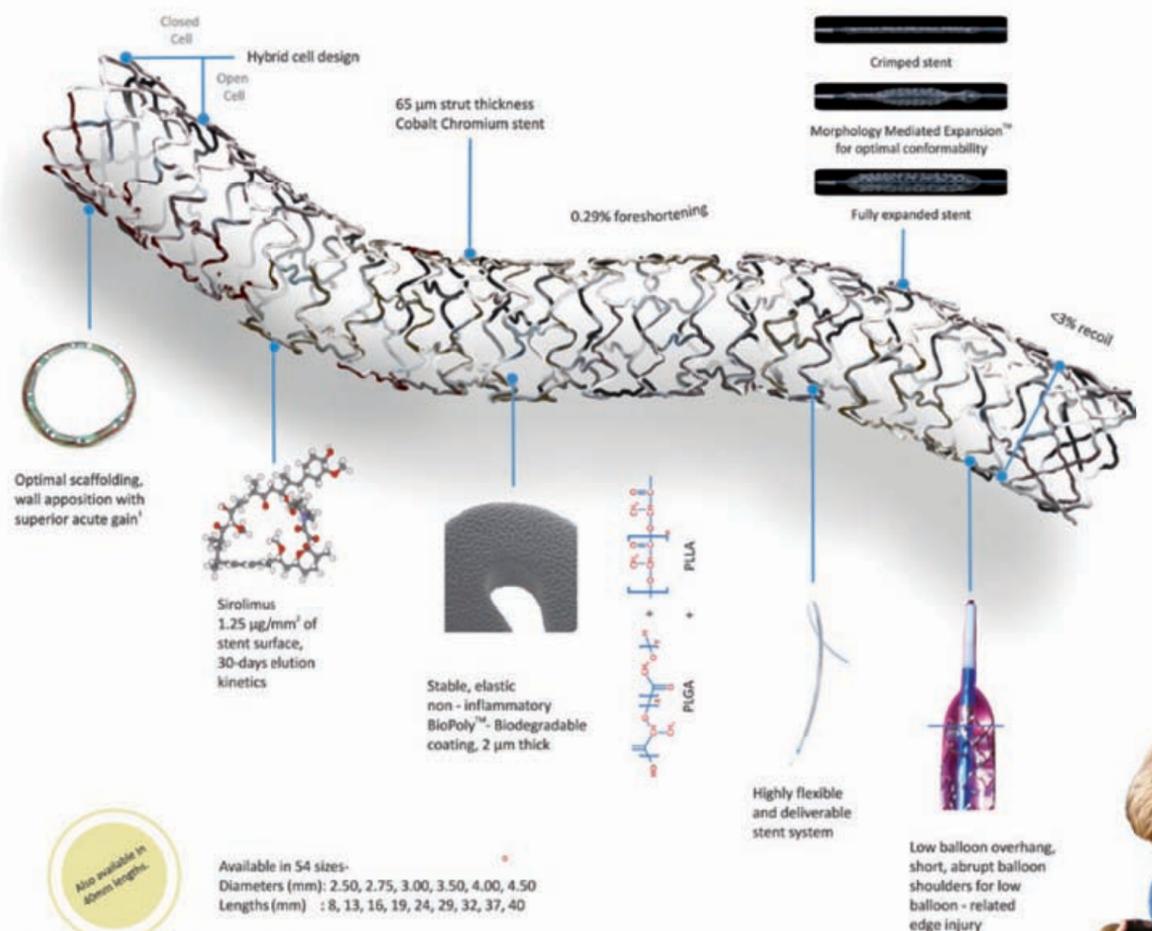


The resultant stent blends the safety of a BMS with efficacy of a DES

SEM pictures of BioMime™ endothelialization in porcine coronary artery, < 30 days<sup>1</sup>



In a preliminary Safety and Efficacy Single Centre Clinical Trial, BioMime™ demonstrated 0% MACE<sup>2</sup> at 6 months



1. Data on file. 2. Dr. Sameer Dani, India/Jae 2010, New Delhi, India, Feb 2010.

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