SOLACI DAILY

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Mexico City
Mexico

SOLACI in Mexico

Another edition of the Congress of the Latin American Society of Interventional Cardiology has come to a close, and once more in this wonderful country, we have had the opportunity to attend one of the best interventional cardiology meetings in the world.

Over the course of the three days of the event, nearly 3,000 doctors, nurses, technicians and representatives from the biomedical industry enjoyed conferences, symposiums, live case transmissions, oral presentations and poster presentations. Most notably, they had the opportunity to interact with colleagues from nearly every country in Latin America, and discussed common problems in different scenarios with the shared objective of helping people with cardiovascular disease to live not only better but also longer.

As in years past, the day-long program PROEDUCAR was conducted with high-level expositions and joint sessions with scientific societies from both America and abroad highlighted the importance of scientific cooperation.

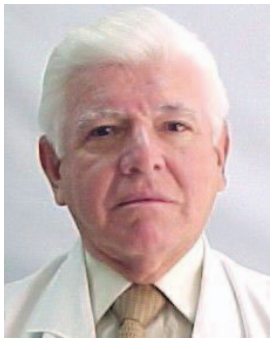
Finally, a special mention for the city of Mexico and the genuine hospitality of its people, thank you for your kindness, your friendliness, your music and why not, your tequilas. SOLACI will miss this city and without a doubt plans to return soon.

Interventional Cardiology in Latin America 20 years after the founding of SOLACI

By Marco Antonio Martinez Rios, MD

As the founder of SOLACI, it is always an honor to speak at these meetings, but it is a special privilege to do it in my country on what is almost its twentieth anniversary. I hope to have a wide range of generations attending this lecture, in which I will spend some wonderful minutes remembering and sharing what the situation in the field of interventional cardiology was like in Latin America back in 1993, how GLACI came to be, and how the name changed to SOLACI. It will be interesting and educational to describe the evolution through the years, remembering the historical and most significant events that predated SOLACI and those that came after, not only in interventional cardiology but also those in the field of structural cardiology and peripheral interventionism.

SOLACI has been growing robustly. It is now the biggest association of its type in Latin America. Its activities are diverse. Most notably, it organizes a high quality international congress, many regional meetings, and has a modern interactive chapter for education (Proeducar). Its web site, as well as the online register of the Latin-American interventional activities, is under continuous improvement.



Life teaches that the cycle of fail-learn-improve is a never-ending process, and with a constructive spirit, I will mention some points that, from my perspective, could be useful in making an even better SOLACI in the years to come.

In two decades, SOLACI has been able to evolve and mature. All this has been possible under different leaderships from diverse nationalities. As its founder, I want to express my gratitude to these cardiologists, all of them close friends, for their dedication, work and time. *(Cont.Pag 3).*

Advances in Mitral Valve Interventions

By José A Condado R, MD

Interventions on the mitral valve apparatus are one of the biggest challenges in today's interventional cardiology. The mitral valve has a complex anatomy, with components that can be affected by multiple mechanism or diseases. Dysfunction of the mitral valvular system results in left ventricular and auricular dysfunction, and later on, pulmonary hypertension and decreased cardiac output with tissue hypoperfusion.

Advances in transthoracic and transesophageal echocardiogram have increased the diagnostic precision of mitral valve disease and have also allowed for the performing of percutaneous interventions with a retrograde approach, guided by live echocardiogram, improving accuracy and decreasing complications.

Multiple new technologies and techniques have been recently added to the list of available options for mitral valve procedures; including a transapical approach using a micro-thoracotomy and the use of the "Impella device" for hemodynamic support.

The mitral valve repair procedures can be divided in:

1. *Design to decrease the size of the mitral valve ring in functional mitral valve insufficiency.*

All these devices use external traction to either:

a. Decrease the size of the valvular ring. That can be performed by:

i. Accessing the coronary sinus (Carillon, Viacor, Monarc, C Cure), the sinus has to have an appropriate relationship between the atrioventricular groove and mitral annulus, without pinching the circumflex artery or its branches.

ii. Implanting a device on the atrial side of the ring (Transseptal) - the Micardia.

iii. Implanting a device on the ventricular side of the annular ring, in the groove *(Cont.Pag 3)*

SOLACI 2012

Esperamos que usted guarde las mejores imágenes de SOLACI 2012

Mallinckrodt/Covidien agradece su presencia en SOLACI 2012. Ha sido una gran oportunidad presentarle nuestros Medios de Contraste y Equipamientos de la más alta tecnología, credibilidad y desempeño. Es una satisfacción ofrecer al mercado productos y soluciones como:

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(Cont. of "Interventional Cardiology in Latin America 20 years after the founding of SOLACI"). Because of them, the society we dream about is a reality, and even more importantly, the future of SOLACI looks bright.

Marco Antonio Martínez Ríos, MD
Managing Director, Instituto Nacional de Cardiología, México.

(Cont. of "Advances in Mitral Valve INTERVENTIONS"). between the outlet valve and left ventricle (arterial retrograde) - the Mitraling or Guiding Delivery System (GDS).

b. Change the mitral valve ring morphology. Returning the normal "oval shape" morphology of the ring, by using an atrial side approach (PS3) or ventricular side approach (i-Coapsys).

All these devices had promising results in early clinical trials, but more experience needs to be obtained. Contraindications include a heavy calcified valvular ring and active endovascular infection.

2. Devices to repair the function of the valve cusps and/or chordae tendinae. The Mitral clip device works by "fusing" the medial segments of the valve (A2-P2), proven in the Everest trial to be non-inferior to surgery on patients with myxomatous degeneration and valve prolapse. Recently, it has been used in patients with functional mitral insufficiency as well.

3. Percutaneous mitral valve replacement. Currently limited to a small number of cases of percutaneous bioprosthetic valves in patients with prior surgically implanted bioprosthetic valves (Valve-in-Valve technique) and animal studies of percutaneous implantation on natives valve using transeptal or transapical approach.

Mitral valve interventions have sustained an exponential growth over the past decades, thanks to advances in imaging studies and technology. In a few years, we will have some methods and devices useful for treatment of chronic mitral valve insufficiency, especially when caused by ventricular volume overload with annular dilation (Functional insufficiency).

Dr. José A Condado R.
Director of Interventional Cardiology
Department of Cardiology
Miguel Pérez Carreño Hospital
Caracas, Venezuelaa

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www.solaci.org

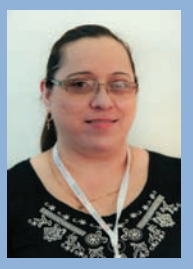
What are your expectations for SOLACI Congress and what does it represent to you?

Ricardo García Soza
Nurse – Specialty in Cardiology – National Institute of Cardiology, Mexico

Learn about the newest innovations in interventional cardiology, specifically related to the heart, peripherals, valve changes, stents and what the new drugs can offer.

Natalia Gonzalez Jaramillo
Head of Research – Santa María Cardiovascular Clinic , Colombia

Study the technological advances with the goal of implementing them in my institution. SOLACI represents the combined strengths of all of the cardiac specialists in the region.



Rosemary Vargas Vargas
Nurse - Hemodynamic Unit–Rafael Ángel Calderón Guardia Hospital, Costa Rica

This is my first time at SOLACI and it's truly a great source of support for us. I am interested in learning about new technology, products, and how the hospitals in other countries work.

Rafael Alberto Alvarez
Cardiologist –Cundinamarca Cardiovascular Hospital , Colombia

Observe the innovations regarding medications and devices, listen to the most experienced voices in cardiology in the region. SOLACI provides us a summary of what we can do throughout Latin America.

	MAIN ARENA TERRAZAS	ROOM CHAPULTEPEC	ROOM MOLINO DEL REY	ROOM ARCOIRIS	ROOM JARDÍN
8:00 - 10:00	Live Cases XXIII - XXVI	Abstract Session III, IV	Clinician's Forum Decisions for Left Main &/or Miltivessel Disease	Mitral Valve Intervention	Congenital Heart Disease
10:00 - 10:15			**Break**		
10:15 - 11:45	Plenary Session III Acute Myocardial Infarction		NIC@SOLACI	Canned Cases III	Congenital Heart Disease
11:45 - 13:15	Live Cases XXVII - XXIX	Complex PCI CTO	Clinician's Forum: Challenging Special Populations (CFR, ELDERY, COPD)		
13:15 - 13:30			**Break**		
13:30 - 15:00		Lunch Symposium sponsored by ASTRAZENECA New Horizons in Antiplatelet Treatments		Lunch Symposium sponsored by ASPEN LABS Optimal Antithrombotic Therapy in ACS- PCI	
15:00 - 15:30			**Break**		
15:30 - 17:00	Complex PCI Left Main: Case Closed	Best Abstract Session V-VI	Clinician's Forum Interventional Therapies in theDiabitec Population		Topics of Particular Interest
17:00 - 19:00	Closing Ceremony & Best Abstract Award				

SOLACI DAILY
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Complications of Radial Access and their Management

By Ricardo Lluberas, MD, FACC

The radial approach has been imposed in the field of interventional cardiology. There is evidence that in relation to the femoral approach, this access has a lower incidence of vascular complications. This reduction in vascular complications could result in a reduction in patient's morbidity and mortality, especially in acute coronary syndromes that are treated with aggressive antithrombotic regimens.

If we respect the completion of the Allen's test before the procedure, the ischemic complication in the radial approach is very unusual. While some experts have questioned it, we believe it is reasonable not to use the radial approach if this test is negative.

The arterial spasm is very frequent and may justify another approach. The best way to avoid it is to prevent it with proper sedation of the patient, and by the use of hydrophilic wires and introducers and catheters of small caliber (F4 or F5). Intra-arterial vasodilator medication is an alternative to prevent spasm (nitroglycerin or calcium antagonists, alone or in combination). If not used as a preventive measure, this medication is very useful at the time of the occurrence of spasm.

Among bleeding complications, large hematomas, pseudo-aneurysms and the need for blood transfusions are rare. They are prevented by proper puncture technique and hemostasis. Pseudo-aneurysms can be treated by compression and eventually with surgery.

The feared and rare compartment syndrome is prevented in the presence of a large hematoma, with arm raised and placement of an elastic bandage. Only rarely is a surgical solution required.

A possible complication is arterial dissection or traumatic injury at the arm or the brachiocephalic arterial trunk. They are prevented by use of hydrophilic guides and catheters and soft guides for the first time to advance to the aortic root and exchange guides when you want to change catheters.

The occlusion of the radial artery has no clinical consequences if we use this approach only in patients with a positive Allen´s test, but you have to take into account that the radial artery could be used in the future in case of need for hemodialysis or as an arterial conduit in case of bypass surgery. Its frequency is variable, but in some series comes up to 10% of cases. A good approach technique and especially a proper post-procedure compression are imperative to avoid this event.

Ricardo Lluberas, MD, FACC
Professor of Cardiology, Montevideo, Uruguay

PCI for Octogenarians and Nonagenarians

By Daniel Berrocal, MD

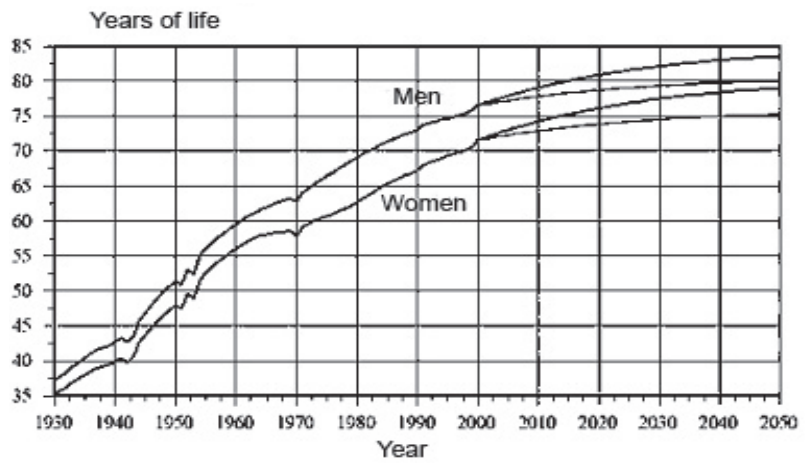
In the decade of the 1930's, the global life expectancy was around 35 to 40 years for men and women respectively. Today, 80 years later, is about 70 to 75 years. If this trend continues we will reach an average life expectancy of between 80 to 90 years. This means that in a century we will have doubled our life span.

Obviously, this does not occur in the same way all around the world. While high-income countries have a life-expectancy of over 75 years, regions such as Africa retain the same expectation of survival as a hundred years ago. It's interesting how our region, despite showing obvious differences regarding health expenditure compared with countries with greater resources, has achieved high levels of life expectancy for most countries.

It therefore follows that octogenarian patients are now fully incorporated into our daily practice and will become even more numerous in the future. When providing treatment, keep in mind that these patients deal with reduced cardiovascular reserve and also have a high incidence of comorbidities ("fragility") frequently added to impaired renal and hepatic function.

Moreover, we must remember that the vast majority of the evidence with which we conduct our daily clinical decision making is based on studies that have systematically excluded patients older than 75 years.

Many studies have shown that the age of these patients is an independent predictor of increased morbidity and mortality. However, studies such as CRUSADE, where we face the reality of these patients who would potentially benefit most from interventions in the context of acute coronary syndromes, are instead the least addressed to an invasive strategy.



While both CABG and angioplasty reported major complications in elderly patients, TAC

TICS-TIMI 18 study revealed in a subgroup analysis that the older the patient is the more pronounced the benefit of early invasive strategy becomes.

Angioplasty seems an excellent choice regarding surgery for revascularization of these patients. It's less invasive and the ability to do it in stages ("staged") is its main strength for these fragile patients.

Undoubtedly during the coming years we will assist in generating several studies to answer these questions about this growing group of patients.

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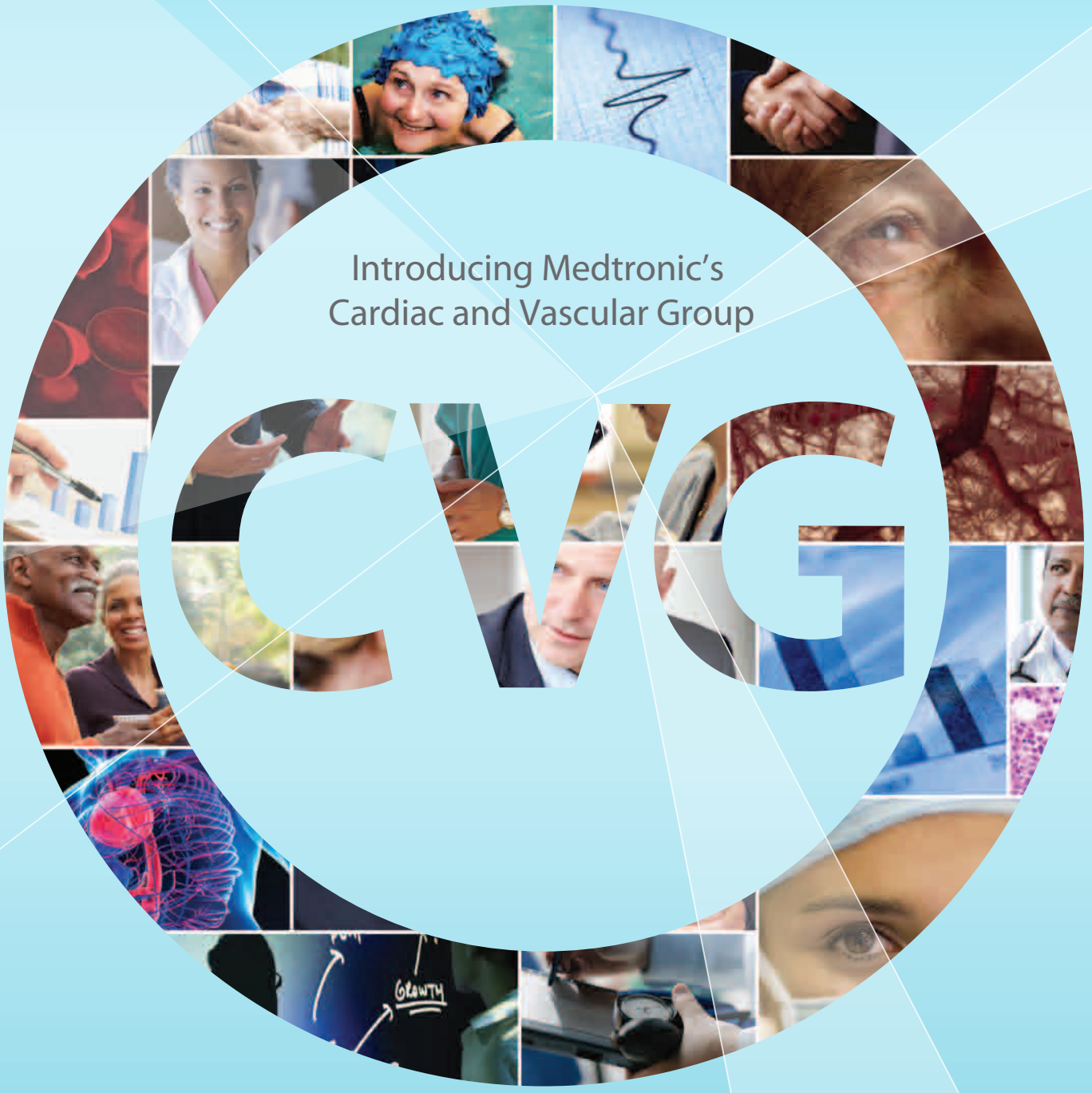

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Timing for Discontinuation of Dual Antiplatelet Therapy

By Roxana Mehran, MD, FACC

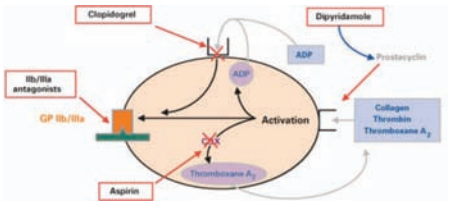
A series of studies have shown an association between drug eluting stent (DES) placement and increased risk of stent thrombosis (ST), attributed to the inhibition of growth rates for the endothelial cells, which results in the decreased endothelial coverage and the delay in the local healing. The greater risk of ST in DES patients led to the mandatory post-PCI use of dual antiplatelet therapy (DAPT) with aspirin and a P2Y12 inhibitor. However, the optimal duration of DAPT remains controversial, as premature discontinuation is regarded as a significant contributing risk factor of death and MI, while prolonged DAPT use puts the patient at greater risk of bleeding complications.

Several studies have produced a great range of results, corroborating the controversial nature of this issue. Some studies highlight the beneficial effect of the longer than 12 months' use of DAPT on major cardiac adverse events (MACE) while other studies have failed to show significant differences in rates of MI and death in 12 versus 24 months of DAPT. Additionally, recent trials (EXCELLENT and PRODIGY), conclude that 6 months' use of DAPT was not inferior to use of 12 months and 24 months respectively, with regards to target vessel failure.

Furthermore, one additional factor that may play a significant role in optimal DAPT duration is the stent characteristics. Some trials have underpinned that the mortality benefit of DAPT does not extend beyond 3 to 6 months in low risk patients who underwent 2nd generation DES implantation. However, the safety and efficacy of shorter duration DAPT post-PCI in low risk patients with 2nd generation DES warrants further investigation. As for BMS, the recent guidelines support the use of DAPT for 1 to12 months, unless the bleeding risk outweighs the antiplatelet benefits.

The uncertainty regarding DAPT duration is mirrored by the conflicting guidelines between the American College of Cardiology (ACC) and European Society of Cardiology (ESC). ESC 2011 guidelines recommend DAPT use for 9 to 12 months for patients with acute coronary syndrome (ACS) undergoing DES deployment. However, according to the 2011 ACC guidelines patients who undergo DES implantation DAPT is recommended for at least 12 months regardless of the patient's clinical status (ACS or non-ACS), with the exception of non-ACS patients with high risk of bleeding.

In summary, the optimal use of DAPT is a multifactorial decision, including procedural characteristics (bifurcation or more complex cases), stent properties (BMS, 1st or 2nd generation DES), baseline characteristics (low vs. high risk), and clinical status (ACS vs. non-ACS). According to the existing knowledge in low risk patients, DAPT use for less than 12 months might be feasible, but unequivocally, more studies are needed to shed light on this debatable issue.



SOLACI 2.0: your needs, our response

By Marcelo Halac, MD

Quietly throughout the course of 2012 we have accepted the challenge set before us by SOLACI to reposition our website. Together with a dedicated and professional team, we have begun this journey and are working to include more academic content. Editorial commentary on recent publications that have a regional impact will also be featured more prominently.

One essential objective of this project has been to strengthen our archives with presentations that demonstrate a high level of academic and communicative value. We understand the importance that each one of you gives to this possibility and we invite you to browse this new section; prepare to be surprised by its content! All you need to do is click on the horizontal Menu (located at the top right of the page) on "Slides."

The incorporation of social media tools like Facebook, Twitter and YouTube is useful in communicating the website's content and the presentation of cases on sites that rely on visual support. Remember that you play a key role in the generation of these materials!

We have also incorporated a series of practical applications that will make your job easier: a scientific calendar where you can review events that interest you and a link that will take you to that event's website. You are also more than welcome to publish your own events in this section in order to spread the word. Another example of this is the "Tips for your Trip to the Congress." There you will find practical information linked back to the official website of the event, the weather forecast for the city in which it will be held, a currency exchange function, a Google map of the actual event site, and a link to tourism websites for both the city and the event itself.

In conclusion, all of these initiatives and proposals aim to keep you informed in a concise and practical manner on scientific updates as well as the practical aspects that will make your work easier. We are waiting for you! Join us: www.solaci.org.

Dr. Marcelo Halac
Web Co-Editor

visit: www.solaci.org

Article by Boston Scientific

Promus Element Stent: Clinical Outcomes

By Pablo Kantor, MD

The first generation of the PROMUS or Xience v stent (depending on the the company selling it) demonstrated excellent efficacy and safety outcomes in numerous studies made in various clinical and anatomic scenarios, making this drug-eluting stent (DES) the "gold standard" that other DES should be compared to.

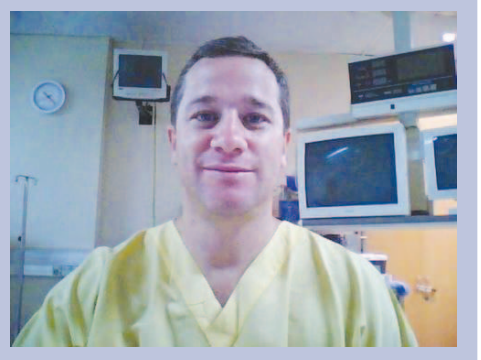
The development of the new Platinum-Chromium ELEMENT platform allowed for the same drug and polymer technology of the PROMUS/Xience v DES to be transferred to the ELEMENT platform conforming the PROMUS ELEMENT DES.

This DES maintained the same Everolimus-eluting concentration and RELEASE kinetics with the same polymer that has proven excellent biocompatibility parameters, with the potential advantage of the new platform in terms of increased radial strength, more flexibility, more conformability and apposition to vessel walls and improved protection of side branches.

These changes required subsequent clinical studies to confirm the feasibility of transferring the PROMUS DES technology to the new ELEMENT platform.

The PLATINUM QCA angiographic study revealed a late-loss rate of only 0.17mm (similar to the previous generation's rate) and a binary angiographic restenosis rate of only 1.1% with the use of the PROMUS ELEMENT DES. However, this 100-patient study had been designed to evaluate angiographic rather than clinical end points.

Instead, the PLATINUM study randomized 1,530 patients to receive the new PROMUS ELEMENT DES vs. the previous PROMUS (Xience v) DES with a non-inferiority design in clinical end points. One-year outcomes confirmed the feasibility of transferring the drug and polymer to the new ELEMENT platform by showing similar combined event (target lesion failure) rates: 3.5% for PROMUS ELEMENT and 3.2% for PROMUS/Xience v (p non inf.=0,0009 / p sup.=0,72). Two-year outcomes of this study were shown in the recent ACC 2012 meeting: not only did the PROMUS ELEMENT DES continue to prove to be "non inferior" to PROMUS/Xience v, but also the need for reintervention was considerably lower (higher efficacy) between the first and the second year with the use of the PROMUS ELEMENT DES as compared to its predecessor PROMUS / Xience v (0.7 vs. 2.2% respectively, p=0.02). Two-year safety clinical end points did not show any significant differences between both DES, but were less with the use of the PROMUS ELEMENT DES (though this difference was not statistically significant): cardiac death 0.9 vs. 1.6% (p=0.33), acute MI 1.6 vs. 2.2% (p=0.54) and stent thrombosis (ARC definite/probable) 0.5 vs. 0.7% (p=0.99), which removes doubts regarding any possible clinical impact related to the assumed longitudinal deformation of the ELEMENT platform observed only in "in-vitro" studies and in sporadic case reports.



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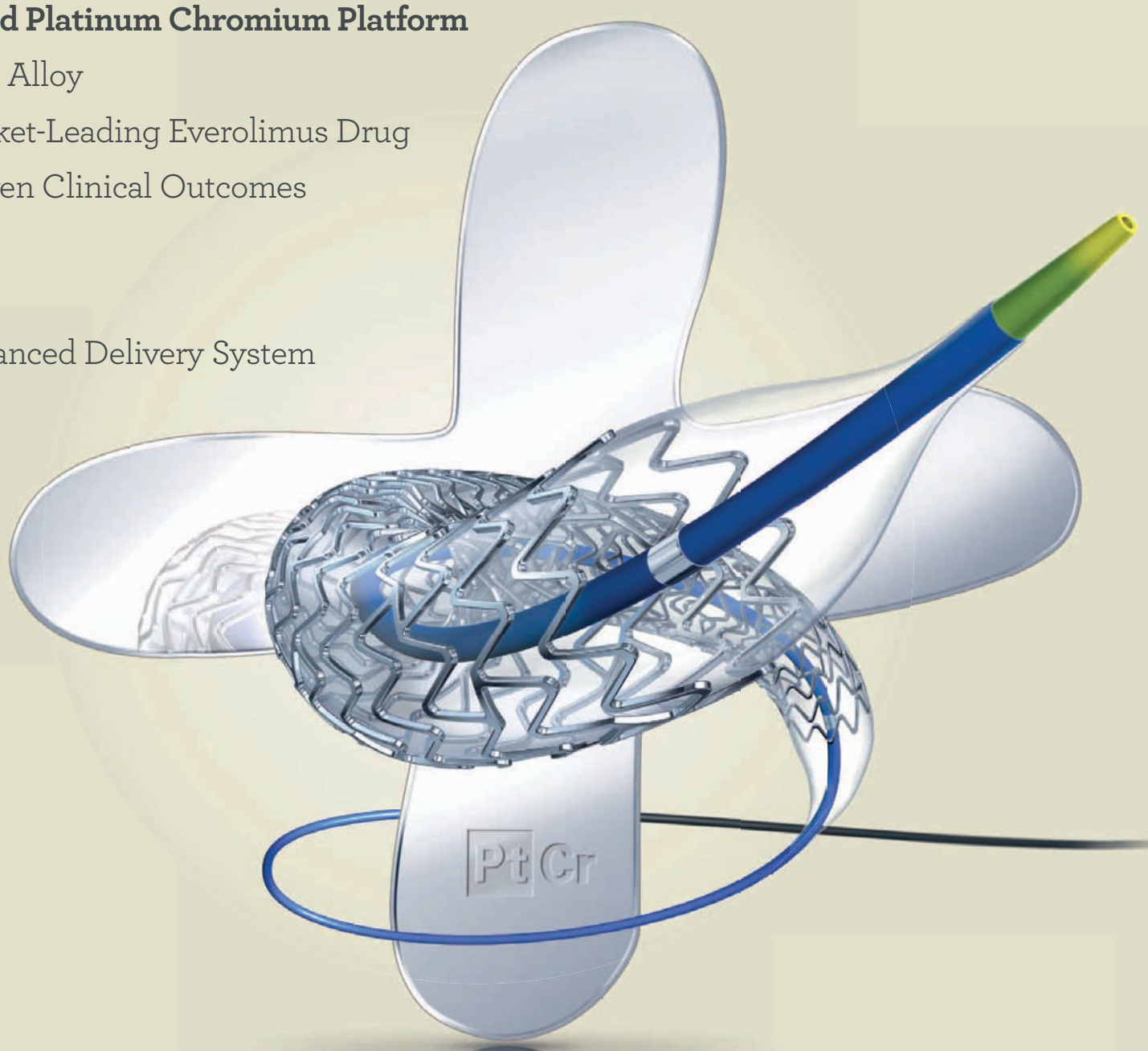

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Article by Medtronic

The Resolute zotarolimus-eluting stent and diabetes mellitus

By Alan Yeung, MD

Based on a prespecified analysis of pooled results from the RESOLUTE Global Clinical Program, the Resolute zotarolimus-eluting stent is the first drug-eluting stent approved by the FDA for specific use in the high-risk population of patients with diabetes mellitus.

Patients with diabetes mellitus (DM) undergoing percutaneous coronary intervention (PCI) often present with more complex coronary artery disease, leading to increased risks for restenosis and adverse events. While drug-eluting stents (DES) have been recommended for PCI in DM patients, no DES prior to the Resolute has been specifically indicated by the US Food and Drug Administration (FDA) for use in this high-risk population.

The Resolute Global Clinical Program

The Resolute zotarolimus-eluting stent (ZES) (Medtronic Inc., Santa Rosa, California, USA) is a new-generation DES consisting of a thin-strut cobalt alloy bare metal stent coated with a durable biostable polymer and the cell-cycle inhibitor zotarolimus. The polymer architecture was engineered to allow for prolonged elution of zotarolimus for more effective inhibition of neointimal proliferation.

The safety and effectiveness of the Resolute ZES have been established in the RESOLUTE Global Clinical Program, which includes 2 large international trials (1 randomized and 1 single-arm) with minimal exclusion criteria and 3 single-arm trials with identical on-label inclusion and exclusion criteria. All 5 Resolute trials were designed with similar endpoints and statistical methodologies, and all required the same regimen of dual antiplatelet therapy. An ad hoc analysis has pooled outcomes for the 5,130 recipients of the Resolute ZES in these 5 clinical trials.

Achievement of the FDA indication for diabetes

To obtain an indication for DM patients for the Resolute ZES, a statistical analysis plan was developed prospectively with the FDA to compare 1-year target-vessel-failure (TVF) outcomes for on-label noncomplex Resolute DM patients against a performance goal derived from literature and from pooled data for the Endeavor ZES.

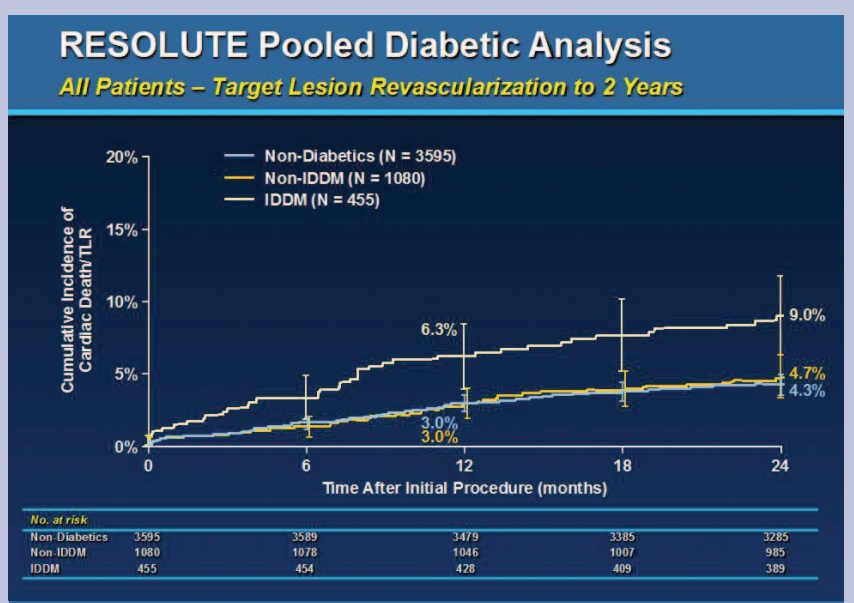
The composite TVF endpoint included cardiac death, myocardial infarction, and target vessel revascularization (TVR). At 1 year, the rate of TVF for the 878 noncomplex diabetic Resolute patients was 7.8% (upper 95% CI 9.51%), significantly lower than the performance goal of 14.5% (p = 0.001), thus supporting the new FDA indication for DM.

Two-year pooled outcomes encouraging for diabetics

For the total population of DM patients, 2-year outcomes were compared with those for 3,595 non-DM patients from the pooled cohort. As expected, rates of major adverse cardiac events were significantly higher in DM patients than in non-DM patients. However, the 2-year incidence of ARC-defined definite or probable stent thrombosis was very low regardless of the presence or severity of diabetes (0.82% for non-DM patients, 0.93% for non-insulin-treated DM patients, and 1.79% for insulin-treated DM patients).

When outcomes were analyzed by treatment with insulin, the incidence of target lesion failure was nearly the same for non-insulin-treated DM patients versus non-DM patients but was significantly higher for insulin-treated DM patients (8.4% for nondiabetics, 8.9% for non-insulin-treated DM patients, and 16.7% for insulin-treated DM patients).

The accompanying Figure breaks out the cumulative incidence for target lesion revascularization by diabetes status. The event rates on this important index of DES effectiveness are low out to 2 years, despite the higher risks and more complex disease presented by DM patients.

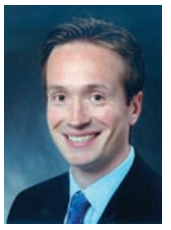


The cumulative incidence of target lesion revascularization at 2 years in the pooled analysis from the RESOLUTE Global Clinical Program.

The Team Behind the Scenes

Challenges for the Future of TAVI

By Jan-Malte Sinning, MD and Eberhard Grube, MD



Aortic stenosis among the elderly is associated with a substantial increase in morbidity and mortality once symptoms such as angina, syncope, or heart failure develop. Since 2002, transcatheter aortic valve implantation (TAVI) has been established as an emerging therapeutic approach for patients with unacceptable surgical risk and a less invasive alternate treatment option for patients at high risk for open-heart surgery. Meanwhile, more than 60,000 patients underwent TAVI procedures worldwide and the dramatic growth in TAVI will possibly continue over the next years. New technology advances promise to simplify TAVI and to improve outcome by reducing the rate of TAVI-specific issues such as stroke, peri-prosthetic aortic regurgitation, acute kidney injury, vascular complications, and conduction disturbances.

However, before indication for TAVI can be expanded to lower risk patients in the future, additional randomized clinical trials about outcome and long-term durability of transcatheter heart valves (THV) are needed. The evidence derived from the PARTNER Trial is that TAVI is the new standard-of-care for inoperable patients with superior outcome compared to conservative management including BAV only. In high-risk patients, TAVI has shown non-inferiority compared with surgical aortic valve replacement (SAVR). Although data from national multi-center registries are very encouraging and fuel speculation about use of TAVI in intermediate risk patients, it is of note that the two commercial available and currently used THVs have not yet been assessed by randomized clinical trials. Therefore, results from the CoreValve US Pivotal Trial and the SAPIEN XT cohort of the PARTNER II Trial are urgently awaited. In addition, long-term durability data showing comparability of TAVI and SAVR are certainly required. Only then, the high attrition rates predominantly attributed to advanced age and comorbities and not to the procedure itself in patients with high or extreme risk consequently may lead to the next step: TAVI in intermediate risk patients. Lessons we have learned meanwhile are that screening, treatment, and follow-up of the TAVI patients have to follow a standardized protocol not only for the better comparability of study data.

Ongoing and future studies will have to show (i) whether TAVI is also non-inferior or even superior to SAVR in patients with severe aortic stenosis at intermediate peri-operative risk, (ii) which access route provides better clinical results, transvascular or transapical, (iii) which access strategy is most viable when a transfemoral approach is denied, and (iv) which THV offers superior results as to implantation ease, vascular access, paravalvular leackage, pacemaker requirement, and durability.

Disclosure: Dr. Eberhard Grube is a proctor for CoreValve/Medtronic

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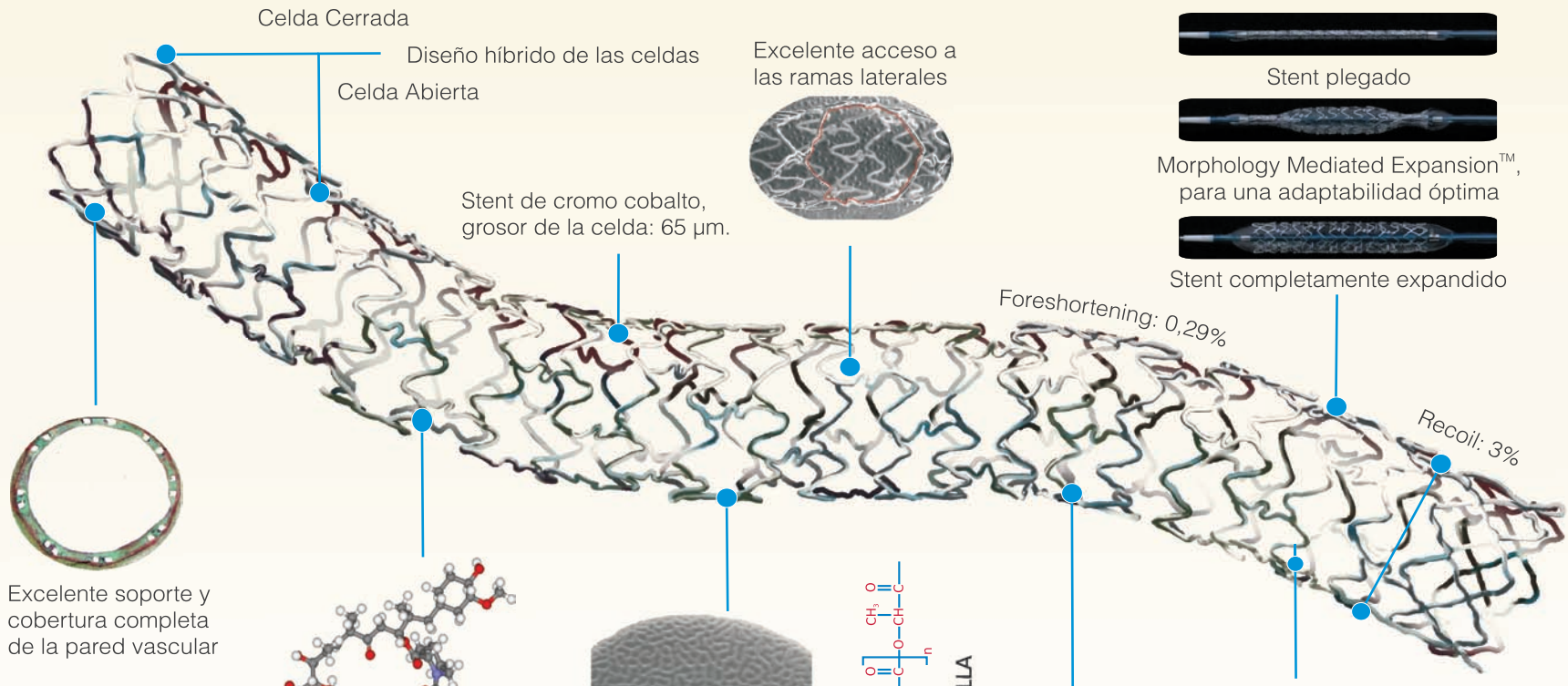

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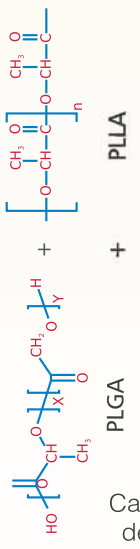

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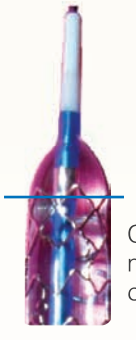

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