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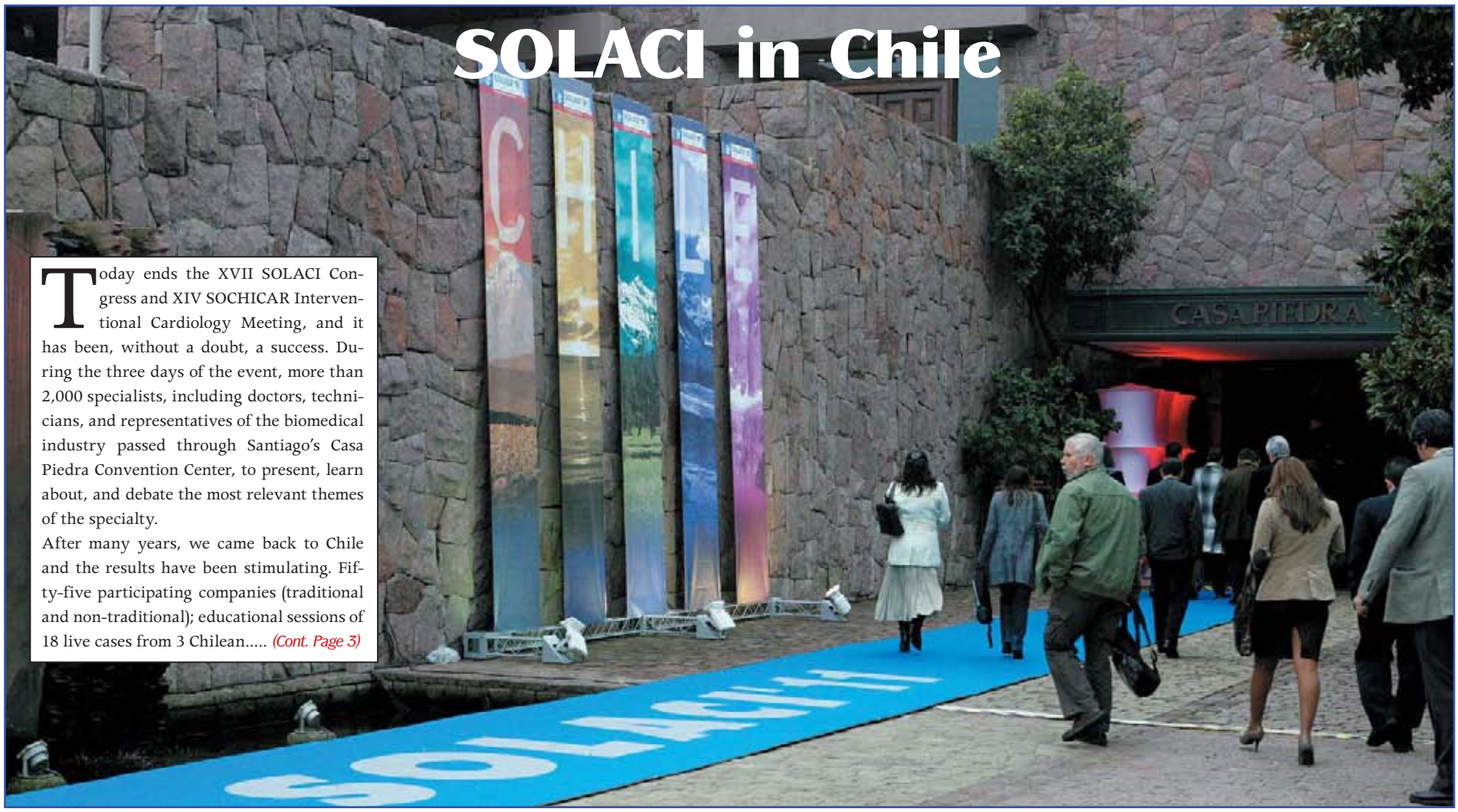
Santiago, Chile



SOLACI in Chile

Today ends the XVII SOLACI Congress and XIV SOCHICAR Interventional Cardiology Meeting, and it has been, without a doubt, a success. During the three days of the event, more than 2,000 specialists, including doctors, technicians, and representatives of the biomedical industry passed through Santiago's Casa Piedra Convention Center, to present, learn about, and debate the most relevant themes of the specialty.

After many years, we came back to Chile and the results have been stimulating. Fifty-five participating companies (traditional and non-traditional); educational sessions of 18 live cases from 3 Chilean..... *(Cont. Page 3)*

SOLACI - Mexico 2012

By José Luis Leiva Pons, MD*

Dear Friends and Colleagues:

On behalf of the Mexican Society of Interventional Cardiology (SOCIME) and its members, I have the great pleasure of announcing that Mexico will be hosting the upcoming SOLACI Congress in August 2012. Mexico City will be the place to meet, and from now I can assure all our interventional visitors that it will be a great success.

Our society is now mature and has grown both in membership and expertise. We are ready to take on the challenge of showing our Latin American friends, as well as the rest of the world, how Mexican interventionalists offer the best quality of care to our cardiac patients. With Dr. Joel Estrada, future president of SOCIME, Dr. Jorge Gaspar, president of the Scientific Committee, and the entire membership of SOCIME, I will have the honor of leading this adventure.

Mexico's, Latin America's, and rest of the world's faculty will be with us. Keeping with SOLACI's philosophy, SOCIME will take good care to organize high academic level sessions, state of the art symposia, case presentation forums, and live case transmissions from the most important national hospitals both in Mexico City and the rest of the country. New stent and imaging technologies will be featured. Topics on coronary, peripheral, structural and congenital heart disease treatment will be deeply discussed. The rapidly developing field of valvular therapies will be of main interest, as well as new pharmacological strategies. Verbal and poster presentations will be the window to show how...*(Cont. Page 3)*


José Luis Leiva Pons, MD

Post PCI Adjunctive Antithrombotic Drugs

By Oscar A. Mendiz, MD*

At the beginning of stents use, despite of an aggressive anticoagulation strategy, there was a 3-4% acute/subacute stent thrombosis (SAT) rate, 10% bleeding and 7-10 day hospital stay.

Thienopiridine introduction for dual antiplatelet therapy (DAT; AAS+ thienopidirine), and stent implantation technique improvement (IVUS guidance) decreased SAT rate, bleeding and shortened hospitalization time.

Aspirin decreases ischemic events, but an ideal dose still remains controversial. CURE & CURRENT-OASIS 7 studies showed that 75-100mg increased bleeding risk.

Among **Inhibitors of the P2Y12 ADP receptor** are thienopiridine (Ticlopidine, Clopidogrel & Prasugrel) and Ticagrelor; all of these are more potent than AAS but have a complementary effect.

DAT duration is still also undetermined, but while Dual Antiplatelet Therapy Study specifically designed to address this issue is conducted, all guidelines recommend it for at least 12 months.


Oscar A. Mediz, MD

Ticlopidina is currently rarely used in occident due to its side effects. **Clopidogrel** is a proactive drug which requires activation. From different studies (CREDO, Armyda, Armyda Reload, GRAVITAS) we learned that loading (or reloading) doses should be..... *(Cont. Page 3)*

SOLACI DAILY
Year Two / Number Three
Friday, August 5th, 2011

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(Cont. of "SOLACI in Chile")

.... centers (HD); 7 industry symposiums; numerous joint sessions: TCT@SOLACI, EuroPCR@SOLACI, Cleveland Clinic@SOLACI, SBHCI@SOLACI, WIN@SOLACI; Brazilian Society of Interventional Cardiology and Hemodynamics; the SOCHICAR Annual Course of Cardiology and also around 200 global and Latin American faculty.

As an activity prior to the Congress, the day-long program PROEDUCAR was conducted, for which more than 100 people registered. Expositions of high educational levels were present, and after the final exam, those participants with the highest averages were presented with prizes to participate in training programs abroad.

A large crowd of clinical cardiologists engaged in interesting discussions about the indications of certain procedures, generating exchanges not only about how but when to do these.

Finally, there was a special mention for the city of Santiago, which, with its imposing snow-capped mountains and the genuine hospitality of its people, created a perfect setting for an impeccable organization.

The live cases were, once again, one of the major attractions of the Congress.

(Cont. de "SOLACI-Mexico 2012")

Interventional Cardiology grows steadily in our Latin American countries.

Nurses and cath lab technicians will also have their own meeting. These "real, behind-the-scenes heroes" are also willing to share their knowledge and skills to assure excellent results to our patients. Interventional Cardiology fellows will also have the opportunity to get together with their teachers and other respected physicians from differing countries. After SOLACI Mexico 2012, they will certainly be eager to continue with their training and become part of this family.

Mexico will not only be for science. I invite everybody to discover our culture, visit our historical buildings, and to treat yourselves with our Mexican wines, beers, and spicy hot tacos, while you listen to the mariachi. Be part of the greatest Latin American interventional experience!!!

Sincerely,

José Luis Leiva Pons, MD
**SOCIME President*

(Cont. de "Post PCI Adjunctive Antithrombotic Drugs")

... 600mg 2 hours prior to PCI to have adequate platelet inhibition. Keeping double doses did not show any benefits and increased bleeding rate (CURRENT-OASIS 7).

Clopidogrel limitations are: slow action onset, significant interindividual response variability and interaction with drugs like proton pomp inhibitors, this phenomenon has not been observed with Prasugrel and Ticagrelor.

Prasugrel has more potent antiaggregation effect, with faster onset and lower interindividual response when compared to Clopidogrel. TRITON-TIMI 38 study showed that patients receiving Prasugrel vs. those who received Clopidogrel had significant primary end point rate reduction (cardiac death, MI, Stroke; 9.9% vs. 12.1%; p<0.001) and SAT (1.13% vs. 2.35%; p< .0001), increasing not surgical bleeding rate (2.4% vs. 1.8%; p=0.03), mainly for those with prior TIA or Stroke, older than 75 and low weight. This drug has been incorporated into guidelines and is currently used excluding those high risk patients' subgroup.

Ticagrelor is a reversible, direct-acting, non-thienopyridine inhibitor of the P2Y12 ADP receptor. It is also a more rapid (2 hours) and potent platelets' inhibitor than Clopidogrel, which has been recently approved by FDA.

In a PLATO study, those who received Ticagrelor (vs. Clopidogrel) had primary end point rate reduction (9.8% vs. 11.7%; p<0.001) without increasing major bleeding (11.6% vs. 11.2%; p=0.43), but increasing not CABG related bleeding (4.5% vs. 3.8%; p=0.03). It also decreased SAT (1.3% vs. 1.9%; p=0.009) and more strikingly, an all cause (4.7% vs. 9.7%; p< 0.01) and cardiac mortality rate reduction was noted (4.1% vs. 7.9%; p<0.01).

Patients receiving Ticagrelor who are undergoing CABG did better than those receiving Clopidogrel.

This drug has been approved by the CE & FDA and incorporated to guidelines for NSTEACS patients (Class I, level of evidence B).

TRITON & PLATO studies share the restriction that Clopidogrel's loading dose was 300mg instead of the currently recommended 600mg.

The rapidly reversible effect of Ticagrelor is beneficial for those patients who have bleeding complications or require urgent CABG; nevertheless, it would become a limitation in the case of early drug discontinuation in patients with poor long-term treatment adherence.

There are other drugs undergoing clinical trials with some promising preliminary outcomes: like **Elinogrel** ($P2Y_{12}$ receptor inhibitor), **Atopaxar and Vorapaxar** (thrombin inhibitors), **Apixaban & Rivaroxaban** (factor Xa inhibitors) or direct thrombin inhibitors **(Dabigatran)**.

Conclusion: better antiplatelet strategy, altogether with a correct stent implantation technique have decreased acute, subacute, late and very late stent thrombosis rate. Although new agents seem to improve outcomes, a tailored strategy should be considered for each patient.

**Chief Interventional Cardiologist at Favaloro Foundation University Hospital*
SOLACI Vice President

Today´s Program

Friday August 5th	Vitacura Auditorium	Cordillera A Auditorium	Manquehue Auditorium	De las Esculturas Auditorium	Cordillera B Auditorium	Del Parque Auditorium	Del Polo Auditorium	Los Andes Auditorium
07.30 - 08:30								Advisory Council meeting 2
08:30 - 10:00	PCR@SOLACI: LTT on How to Treat a Patient with Coronary Bifurcation Lesions	Abdominal Aortic Aneurysm	Acute Myocardial Infarction	Symposium on Miscellaneous Congenital Heart Disease Topics	Neurointerventions	Stent Grafting. Best Edited Cases VI.	**08:30 - 12:30** Posters Session V	Latinamerican Council meeting
10:00 - 11:25		Other Endovascular Interventions	Symposium on Renal Failure	Best Edited Cases VII.	Cardiac Failure in the Coronary Unit	ProEducar Session III: Endoluminal Treatment of Aortic and Lower Limbs Diseases		
11:30 - 12:25	Abstracts Session IX: Structural Interventions.	Abstracts Session X: Coronary Interventions	Best Edited Coronary Cases VIII	Abstracts on Congenital Heart Disease III	Breakthroughs in Interventional Cardiology	Abstracts Session XI: Basic Research		Abstract Session XII: Peripheral Interventions
12:30 - 12:55	Keynote Lecture: Future Perspectives of Percutaneous Implant of Aortic Valve. Conference by Prof. Eberhard Grube	Keynote Lecture: PFO Closure. Conference by Dr. Horst Sievert					**12:30 - 16:30** Posters Session VI	
13:00 - 14:25	BSCI: Innovation in Interventional Cardiology (Lunch Symposium Sponsored by BSCI)	Antiplatelet Therapy Advances in ACS and PCI: Advances in Therapy to Improve Outcomes (Lunch Symposium Sponsored by Eli Lilly)		Symposium on Hybrid Therapy				
14:30 - 16:25	Best Edited Cases IX. Complications in Coronary Angioplasty	Structural Cardiopathies. Best Edited Cases X		New Technologies Symposium				
16:30 - 17:00	Closing Ceremony. Awards Ceremony.							

Article by CID

Current DES technology and DAT issues

In patients undergoing percutaneous coronary interventions (PCI), "first-generation" drug-eluting stents (DES) represented a breakthrough technology, showing a dramatic reduction of restenosis rates as compared with bare-metal stents (BMS).

According to astonishing results gathered from first pivotal trials, DES have been subsequently widely used for PCI in clinical practices. DES were introduced in the market in association with a mandatory dual antiplatelet therapy (DAT, thienopyridine and aspirin) course, initially prescribed for a period of 3 to 6 months, aiming to avoid clot formation inside the stent (stent thrombosis).

After the first period, additional studies, even those of small sample sizes, reported increased stent thrombosis, mortality and myocardial infarction events associated with DES.

Autopsy studies on patients who died suddenly after PCI with DES confirmed the latter as responsible for delayed vessel healing, late-term media remodelling with aneurisms formation, eosinophil vessel wall infiltration and persistent peri-struts thrombus deposition. Moreover, polymers, carrying-on antiproliferative or cytotoxic drugs, were found to not be biologically "inert" as firstly hypothesized, but responsible for adverse clinical events in patients with previously implanted DES, particularly after the anti-inflammatory effect of the antiproliferative drug totally disappeared. Consistently, "anecdotic" reports described abrupt thrombotic closure of previously implanted DES after DAT withdrawal.

Despite the fact that data from registries and meta-analyses found no differences in the risk of early or late stent thrombosis between DES and BMS, a risk excess growed-up at longer follow-up (>1 year, very-late stent thrombosis). A constant stent thrombosis rate increase of 0.5–0.6% per year was confirmed for first generation DES.

Accordingly, a U.S. Food and Drug Administration advisory panel supported the empiric recommendation of 12-month DAT after DES placement, furthermore stating that these prescriptions had to be incorporated into the product's instructions of use.

Today a mandatory 12-month DAT period is adopted as a "default strategy" after DES implantation, attempting to minimize the risk of abrupt thrombotic events until the stent struts re-endothelialisation is completed.

Unfortunately, optimal DAT duration is still a matter of debate, since anti-proliferative drugs absorption kinetics are different and unpredictable; moreover, the persistence of polymers after complete drug elution should represent a life-long risk for patients.

As a counterpart, DAT time window represents a limit for DES use, especially in patients with several comorbidities, with contraindications to long term DAT, requiring major surgery within 1 year after DES deployment or living in the so-called "Third World" where DAT costs are not sustainable for all patients.

Recently developed guidelines on myocardial revascularization stated that elective major non-cardiac surgery should be postponed for at least 12 months in patients undergoing DES implantation and that operators should restrain from using DES in patients who are supposed to undergoing near-term surgery.

Recent data showed that at 5-year follow-up, one quarter of DES-treated patients undergo at least 1 non-cardiac surgical procedure and up to 10% of patients had at least 1 major bleeding episode.

(Figure 1)

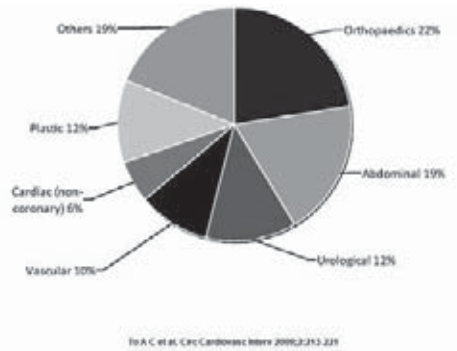
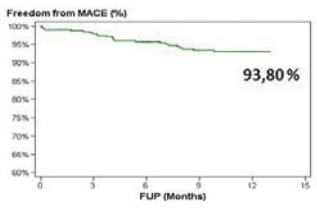


Figure 1. Occurrence of noncardiac surgery during the 5-year follow-up, divided into subgroups.

According to progressive worldwide population "ageing," we are conducting PCI in older patients with several comorbidities and at very high bleeding risk that, according to the above-mentioned reasons, are not DES candidates. Thus, it takes big effort on developing different, much more "patient-friendly" DES technologies.

Among those commercially available, the development of polymer-free platforms, avoiding the inflammatory process going on after drug elution, represents one of the most promising strategies.

In particular, a polymer-free DES technology – OPTIMA DES, which was developed in the last years by Carbostent and Implantable Devices (CID, Saluggia Italy) could represent an important answer to the above-described issues. The Multicentre registry with Antiplatelet TReatment two – sIX months (MATRIX) registry demonstrated the safety profile of polymer-free, carbofilm-coated, tacrolimus-eluting stenting in real-world patients, irrespective of DAT time window, with good efficacy at 1-year follow-up. Accordingly, recently data from the Multicentre OPTIMA Carbostent use in paTients treated with two-month dual antiplatelet theRapy after IndeX procedure (MATRIX II) supported previous data, furthermore reinforcing the possibility that safety should not be traded off for efficacy.



	392 Pts 2 months DAT	Total
Acute Thrombosis	1	0,2%
Sub-acute thrombosis	0	0%
Late Thrombosis	0	0%

(Figure 2)

MATRIX II registry - MACE (Above the image) = Death, Miocardial Infarction and Target Lesion Revascularization (Below the image)

This could allow escaping from the prolonged "DAT-dependence" after DES implantation.

Given the encouraging data gained from these multicentre experiences, it seems practical to design and conduct further studies corroborating the clinical impact of this alternative DES strategy that will expand the basis of patients that could benefit from this therapy.

Interview with Dr. Jorge Leguizamón

By Jorge H. Leguizamón, MD*

What can you tell us about the practice of unprotected left main percutaneous revascularization?

Since the advent of drug-eluting stents (DES) there is a growing interest in percutaneous coronary intervention (PCI) of the unprotected left main coronary artery (ULMCA). In Argentina, this practice is rapidly gaining recognition and the number of patients who receive a stent in ULMCA is increasing.

Which was the purpose of the REMAR-T study?

REMAR-T is the first Multicenter Registry of Unprotected Left Main Coronary Artery Stenting in Argentina.

The aim of the study was to evaluate early and late results as well as predictors of major adverse cardiovascular events (MACCE) after ULMCA PCI in Argentina.

How many patients did you include and what were the results?

This registry included 340 patients (p) after ULMCA stenting enrolled between 2003 and 2009 in nine centers in Argentina. The median follow-up was 13.0 months. Patients with STEMI were excluded.

Technical success was 97.9 per cent, with DES being used in 55.0 per cent of the cases. Distal left main disease was 60.4 per cent. Nevertheless a simple stenting technique was performed in 73.2 per cent. In-hospital death was 3.2 per cent (CI 95 per cent 1.7-5.6) for an estimated logistic EUROSCORE mortality of 5.5 per cent. The incidence of MACCE was 21.8 per cent (CI 95 per cent 17.6-26.4); total mortality rate was 12.6 per cent (CI 95 per cent 9.4-16.5 per cent) and death from cardiac cause 7.5per cent (CI 95 per cent 4.9-10.5 per cent). The only independent predictor of mortality was logistic EUROSCORE >10 per cent (OR 2.24, p=0.02). Independent predictors of MACCE were the use of bare metal stents (BMS) (OR 2.19, p=0.009), left main diameter <3.5 mm (OR 2.07, p=0.02), logistic EUROSCORE >10 per cent (OR 1.98, p=0.01) and complex stenting technique (OR 1.89, p=0.04). After adjustment for baselines characteristics, the benefit of DES utilization regarding MACCE rate wasn't modified (Cox p 0.009).

Could you summarize the main findings of the study?

PCI of ULMCA in Argentina shows promising results. Logistic EUROSCORE was an independent predictor of mortality and MACCE. The use of BMS, left main diameter and stenting technique were predictors only of MACCE.

Which is in your opinion the importance of a local registry of ULMCA?

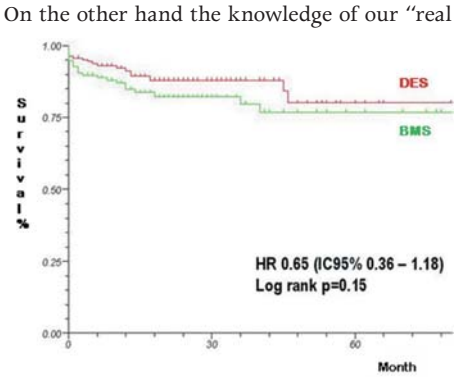
Having a Multicenter Argentine Registry whose results are equivalent with the leader in international trials leads us to compare those with our "real world" left main angioplasty. This enables us to go forward with more ambitious and better-designed clinical investigations.

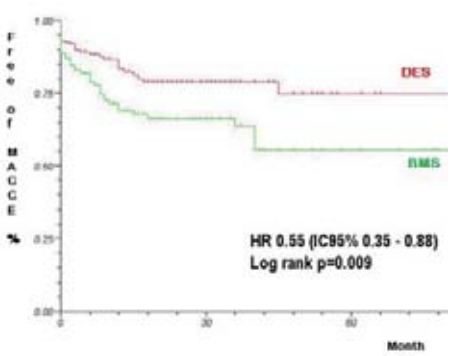
On the other hand the knowledge of our "real world" will help to offer each patient the best therapy and will show us the most appropriate way for doing future interventions.

The late outcome of the Syntax trial and the results of other ongoing trials will aid to determine the role of the PCI in unprotected left main coronary artery disease.

Note: REMAR-T was accomplished by J Leguizamón, L Valdivieso, O Mendiz, A Rodríguez, E Picabea, F Cura , D Grinfeld, A Alvarez, G Andersen and F Azzari.

**Head of Interventional Cardiology in Clinica Bazterri-*





Drug Coated Ballons in Coronary Artery Disease

By Juan F. Granada, MD*

In the last several years, drug coated balloons (DCB) have emerged as an important therapeutic alternative in the treatment of coronary in-stent restenosis and de novo peripheral vascular disease. With the use of this technology, a short-term transfer of antiproliferative drugs into the vessel wall is achieved without the requirement of a permanent drug delivery system. Early data with regards to the DCB technologies for use in the coronary territory was derived from small clinical trials using Paclitaxel coated balloons (PCB) in the setting of in-stent restenosis. Recently, new data is emerging for the use of DCB in de novo lesions and other specific coronary applications.

Several technical features make DCB a viable alternative in the interventional cardiology field. First, by using a larger surface area for drug delivery it is possible to achieve a larger and homogeneous drug transfer. Second, it is possible that avoiding the ongoing presence of a polymer, increased biocompatibility can be achieved. Third, from a technical point of view, the familiarity with the technology allows an opportunity for their use in situations where DES use is problematic or less effective such as ostial disease, small vessels, bifurcations, diffuse disease, etc.

One of the lessons learned early in the development of this technology was the need to use a "carrier" to enhance drug transfer. Most of the carriers currently in use are non-polymeric in nature and appear to enhance the transfer capabilities of Paclitaxel. Sirolimus and its analogues have also been tested and found, at least at the pre-clinical level, to have a profile that might allow their consideration as alternatives to Paclitaxel. Clinical and angiographic data of several clinical studies using different DCB technologies in the coronary territory have been already published (Figure 1). All the positive data presented to-date regarding the use of DCB has been in the setting of in-stent restenosis or de novo peripheral vascular disease lesions. Another group of investigators, utilizing a similar platform (SeQuentTM Please, B. Braun) have completed a series of studies (PEPCAD trials) in order to test the technology in different coronary settings (Figure 2). In the Valentines trial (Dior II, Eurocor), 250 patients with ISR of a BMS or a DES underwent DCB treatment and the overall TVR rate at follow up was 9%. Other clinical trials are under development using different DCB platforms and targeting different clinical applications.

In the future, while the new clinical data still emerges, the current clinical application of this technology must remain limited to in-stent restenosis, in which almost all platforms have shown to be successful compared to other clinically approved coronary technologies. Larger randomized clinical trials will hopefully show the potential clinical applications of this technology and its role in today's cardiac laboratory.

*Executive Director and Chief Scientific Officer, Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation. Assistant Professor of Clinical Medicine, Columbia University Medical Center, New York, NY.

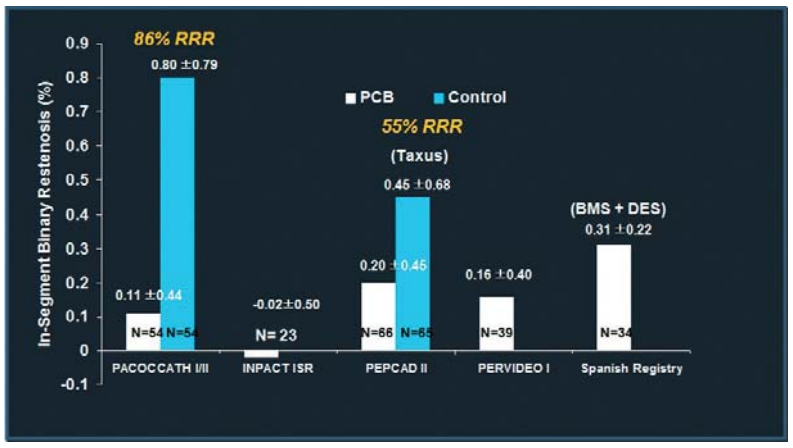


Figure 1. Angiographic late loss in several small clinical trials of coronary ISR. PACCOCATH (Medrad Inc), INPact ISR (Invatec-Medtronic), PEPCAD II (BBraun), PERVIDEO (Lutonix), Spanish Registry (Eurocor).

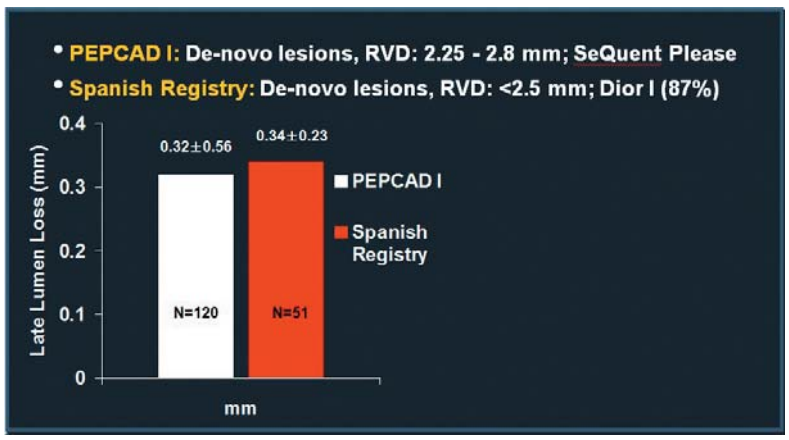


Figure 2. Angiographic late lumen loss in the PEPCAD I and the Spanish Registry in small vessel PCI.

Article by Medtronic

DEB (DRUG ELUTING BALLOON)- A NEW TECHNOLOGY FOR CLI

By Felipe Nasser, MD*


Felipe Nasser, MD

CLI is a chronic arterial disease with clinical signs of rest pain, ulceration, and gangrene and diagnostic evidence of hemodynamic and perfusion insufficiency in the foot.

The final andrapidly-evolving stage after multi-year, long lasting, neglected, and undiagnosed condition is the chronic disease.

The burden of CLI is huge and largely undiagnosed and undereported. Primary amputation is still the first line of approach in almost 50% of the cases.

The gap between size and gravity of this unmet need and the number / availability of diabetic foot centers is even bigger. At the first signs of rest pain and ulceration, CLI evolves rapidly towards a nefast outcome.

Prevention and early diagnosis remain the two key and most effective solutions, as well as public awareness and education, and pre-sceening programs to the general elderly and diabetic population).

This being said, DEB has been proposed as a promising solution to deal with long lesions and occlusions as typically encountered in peripheral vascular disease.

While BTK and SFA stenting remains a bail-out strategy in most practices, DEB has shown a reduction in restenosis rates based on angiographic rates and TLR and constitutes a promising option for the treatment of restenosis.

With the emerging consensus of using endovascular as first-line therapy for lower limb arterial disease, a "stent-free" strategy (with "strict provisional stenting") would be preferable to best preserve the arterial conduits for future options, including surgical bypass.

This new technology is based on PTA balloon platforms with a special coating made of an another well-known antirproliferative drug "paclitaxel." Paclitaxel use in a DEB format provides a potent drug with sustained activity without the use of DES. While PTX is undesirable for coronary DES, it is the ideal drug for DEB.

In DEB technology, no polymer or stent is required for delivery implant. Paclitaxel is transferred to the vessel wall in crystaline form, and because it is transferred in this state, it then experiences extended release to the intima.

Positive and consistent clinical results have been shown in patients with peripheral vascular disease treated with DEB.

*Interventional Radiology Department, Hospital Israelita Albert Einstein - Hospital Santa Marcelina
SÃO PAULO - BRAZIL

Article by Meril

Novel MitsuTM – Merilimus Eluting Coronary Stent System

From the rich R&D portfolio of Meril Life Sciences, MitsuTM comes as a fresh thought. Its ground breaking polymer free DES concept employs 40µm thin stent and a unique new formulation that is built on nano-technology based drug delivery system.

The base stent has a hybrid cell design geometry inspired from Meril's successful BioMimeTM platform. The struts and their interconnecting elements have been configured to provide equivalent radial force as an 80µm stent would generate and placement of cells ensure no compromise in radiopacity of the thin stent.

A novel anti-proliferative drug "Merilimus" has been developed which is a Sirolimus analogue with better lipophilicity and broader therapeutic range. The drug is formulated with solid lipids and the mixture is homogenized to create particulate that are well under 300nm.

Small nano-particulates have been noted to diffuse as far as medial and adventitial layers within the arterial wall. This formulation is programmed to release the drug at variable time points such that a burst during the first 2 weeks ensure high tissue concentration of the drug which resolves over a period of 1 month. The remaining drug is programmed to elute over a period of 45-60 days thus ensuring optimal drug cover subsequently.

Thin struts, polymer free formulation and a novel new limus bring the promise of resolving the holy grail in DES technology, that is – restenosis and stent thrombosis.

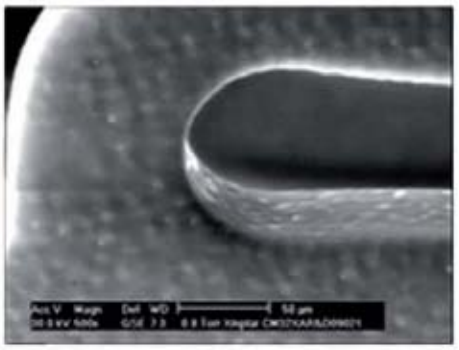
Meril Life Sciences is a young, dynamic medical device development and manufacturing company based in India at Vapi. www.merillife.com

The company was established in 2006 and has been working on creating low injury coronary stent systems which have superior conformability and endothelialize early.

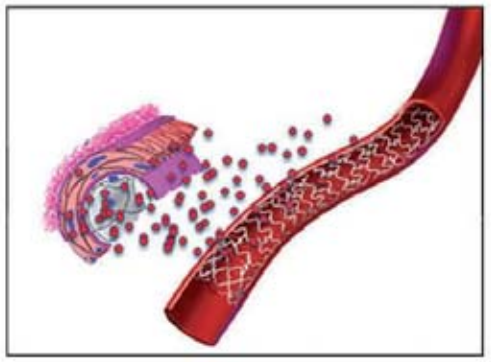
Meril's current portfolio are all CE marked -

- BioMimeTM - Sirolimus Eluting Coronary Stent System
- NexGenTM - Cobalt Chromium Coronary Stent System
- CryptonTM - Stainless Steel Coronary Stent System
- MozecTM - Rx PTCA Balloon Dilatation Catheter
- HaikuTM - Inflation Device

Unique Formulation - Solid lipid nano-spheres (SNL) consisting of Merilimus + Lipid (<300nm)



SEM Image of Stent struts coated with nano-formulation



SLN rapidly leave stent and enter vessel wall with prolonged tissue residence time

Average particle size 165nm. High nano particle stability

Article by Cordis

CYPHER® Stent: the Power of an Icon

By Dayse Mainfeld Repsold, MD

In 1975, Rapamycin was first isolated from a soil microorganism Streptomyces hygroscopius and was classified as an immunosuppressive drug with anti-proliferative and anti-inflammatory characteristics.

In 1995 began the development of the CYPHER with the creation of a Stent Therapeutics Team. This team collaborated with internal and external Johnson & Johnson partners to develop a therapeutic strategy for the prevention and treatment of restenosis.

CYPHER was the first stent to utilize the drug Rapamycin, also known as Sirolimus, creating the concept of the Drug Eluting Stent. It was then the breakthrough technology that would change the field of cardiovascular care.

In 2003, when the FDA approved the CYPHER stent in the United States, the Department of Health and Human Services Secretary, Mr. Tommy Thompson, declared that: "This approval represents a significant step forward in the treatment of heart disease. Patients who receive this device will need fewer repeat operations to unclog arteries, which can make a real difference in the quality of their lives."

Since its introduction, CYPHER has been used to open the blocked arteries of more than 4 million people around the world and helped them restore activity to their lives.

CYPHER has been evaluated in more than 55,000 people in over 80 clinical studies, making it one of the most researched devices in medical history.

CYPHER has been shown to dramatically improve clinical outcomes. And in past years, the studies further support the heart stent's remarkable level of safety and performance. Through years of the clinical research in Intervention Cardiology, no DES showed superiority to the solid and outstanding results in all subgroups of patients of CYPHER or could sustain the edge on the treatment of complex patients in the long-term.

Cordis should take pride in the creation of the DES market and could proudly say that this commitment transformed expectations for patients and practitioners in the field of interventional cardiology into a success story, and that they will never forget that the CYPHER has helped to save the lives of millions of people.

The Interventional Cardiologists should be honored to be part of a generation that has the privilege of participating in the creation of a new technology that was and still is able to save so many lives and keeps life going for so many years.

CYPHER documents in our memory success and advancement in clinical research, which was the precursor, leaving a legacy that we hope will be followed by all who allow themselves to corroborate on the responsibility of medicine at its core.

Article by Medtronic

What are your expectations for SOLACI 2011?

Dr. Gloria Mohamed
(Interventional Cardiologist, Hospital Carlos G. Durand Buenos Aires, Argentina)
"I was incentivized above all by the exchange with my Latin American colleagues. I also want to highlight the contribution that live cases produce, as it's something we face day after day."

Dr. Bernhard Westerberg
(Interventional Cardiologist, Hospital de Antofagasta Antofagasta, Chile)
"I came to better understand the developments relative to the high prevalence of non-coronary diseases. I am particularly interested in the discussions on this topic."

Karet Escalona
(Nurse, Hospital Clínico de la Universidad Católica de Chile Santiago, Chile)
"I want to learn about the advances and developments in my profession, nursing, and especially focus on the percutaneous aortic valve."

Dr. Ricardo Marin
(Cardiologist, Hospital Carlos Van Buren Valparaíso, Chile)
"I am interested in evaluating the work being done throughout Latin America, the techniques, and the level of progress that has been made regarding invasive procedures."

Experience and Technology Advancements in Transcatheter Aortic Valve Implantation

Clinical experience and technology improvements with the Medtronic CoreValve Transcatheter Aortic Valve Implantation (TAVI) System yield improved procedural performance and increase importance of long-term valve durability

By Holly Vitense, PhD

Use of transcatheter aortic valve implantation (TAVI) for the treatment of patients with severe aortic stenosis (AS) is growing rapidly with more than 15,000 CoreValve TAVI devices now implanted worldwide. Surgical aortic valve replacement (SAVR) has been the gold standard treatment for severe AS, providing symptomatic relief and prolonging life. However, up to one-third of AS patients are denied surgical SAVR due to the presence of significant risk factors such as advanced age, non-cardiac co-morbidities or frailty. TAVI has emerged as a viable treatment alternative for these patients, demonstrating significant survival improvements when compared to medical management in inoperable patients, and similar survival rates to SAVR in a high surgical risk patient population.

Recent clinical studies show reductions in TAVI complications and improvements in overall TAVI outcomes. These improvements are likely the result of several factors including enhancements in implanter experience, procedural technique, technology, and patient selection. Several studies have reported a learning affect associated with TAVI experience. For example, Lange, et al, report a significant improvement in CoreValve positioning and reduction in complications with implant experience. In addition, new implant approaches, such as subclavian implantation of the CoreValve system, can potentially reduce vascular complications in patients with poor iliofemoral access. Technology enhancements, such as the new AccuTrak delivery system, have been shown to improve stability and accuracy of implant depth, reduce the need to manipulate the valve during deployment, and reduce pacemaker implantation following the procedure. AccuTrak was found to contribute to the reduction in permanent pacing from 35.5% to 14.0% at one center.

Holly Vitense, PhD

Greater device experience and technology advancements have improved clinical outcomes and may extend TAVI to a broader patient population, expanding treatment beyond the highest risk patients served today. As procedural outcomes improve and lower-risk patients are considered for TAVI, additional emphasis will be placed on valve durability. The CoreValve system is uniquely designed for durability. The tensile strength, pliability and thin profile of CoreValve's porcine pericardial tissue are optimal for TAVI performance. Porcine pericardial tissue provides statistically similar tensile strength to bovine pericardial tissue and strength that far exceeds peak physiologic stress. However, porcine tissue is half as thick as bovine and well-suited for delivery in a small profile catheter. In addition, the increased valve height and more deeply cut leaflet design of CoreValve lengthen the free margin to reduce stress and increase coaptive surface area. Load is absorbed equally by each point on the leaflet commissures. Valve designs that reduce leaflet stresses are likely to have improved performance in long-term applications. In addition, the supraanular valve function in CoreValve decouples the valve from the native annulus shape and minimizes ellipticity at the valve level, reducing the potential for bending and buckling stress. The benefits of these design factors are demonstrated through valve testing. The CoreValve system is tested to the same 200 million cycle standard as surgical valves, the equivalent of 5 years. In testing, minimal macroscopic valve wear seen on leaflets showed no evidence of internal pericardial leaflet delamination or collagen loss even after 200 million cycles. This testing shows evidence of long-term durability, which will be further determined with long-term clinical experience.

To learn more about TAVI and the Medtronic's CoreValve system, come to the Medtronic sponsored symposium (The Future of Interventional Cardiology) at SOLACI Congress.

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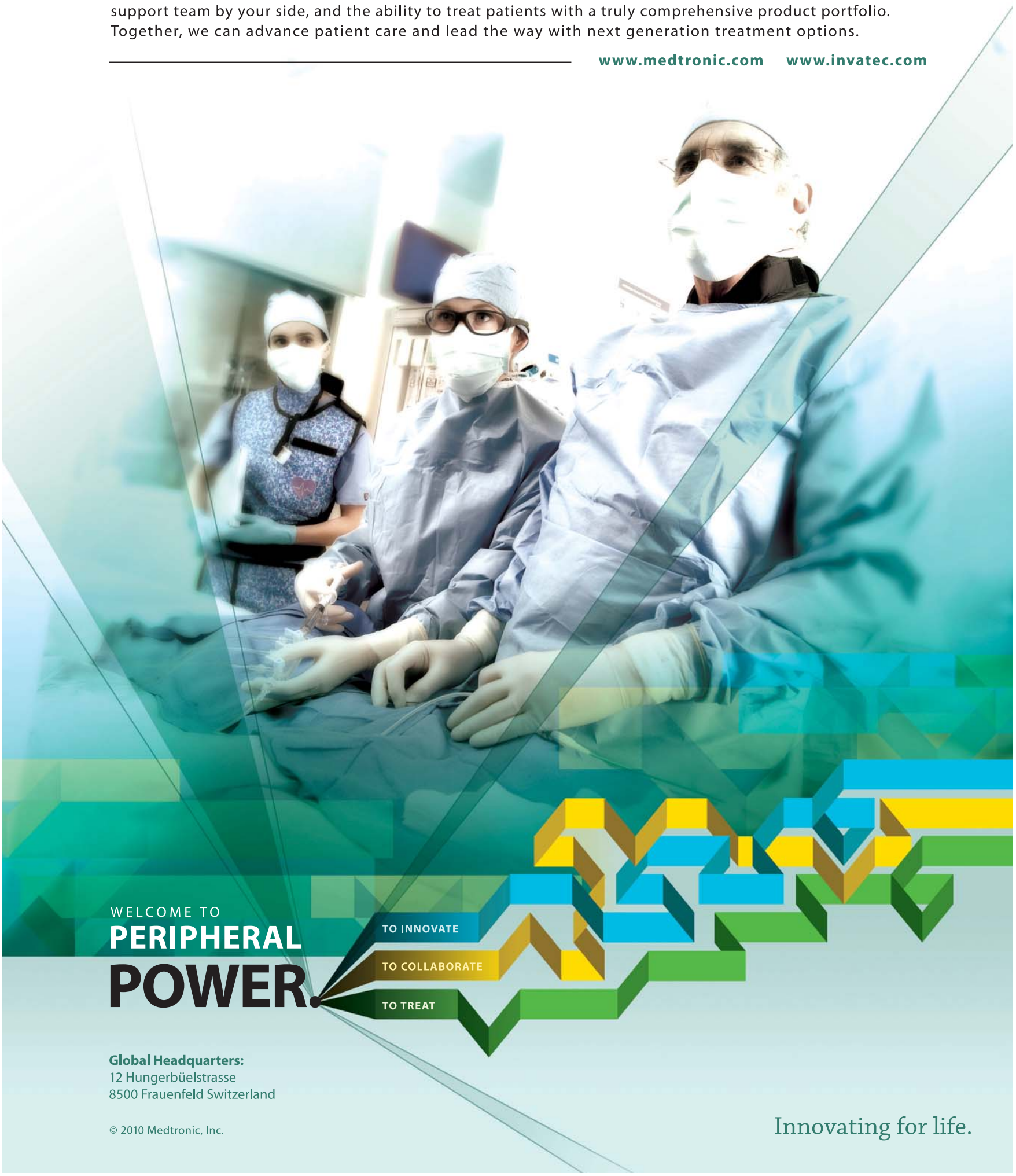

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