



SOLACI DAILY

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Buenos Aires

República Argentina

The Official Newspaper of SOLACI Congress

Large number of attendees in SOLACI '10



Today is the last day of the SOLACI – CACI 2010 Congress in Buenos Aires, and we are proud to say that this year we count with a great number of attendees in the event.

The XVI Congress of the Latin American Society of Interventional Cardiology and the XX Congress of Argentine College of Interventional Cardioangiologists welcomed national and international experts in the area, colleagues who belong to other disciplines of cardiovascular and vascular medicine, and a great number of nurses and technicians.

Our vast number of visitors is able to attend an exciting program filled with a great number of lectures given by the most important professionals in the area and 25 high definition live cases broadcasted from four centers in Buenos Aires. In addition to this, we count with 3 different Exhibition Halls to be walked around, interactive workshops and discussion boards on different essential topics.

We hope that your enthusiasm is compensated with a very pleasant and teaching experience, and you enjoyed your stay.

As well, we look forward to welcoming you to SOLACI '11, which will take place in Santiago de Chile at the Casapiedra Convention Center from Wednesday August 3rd to Friday August 5th.

Interview with Dr. Dussailant

Can you provide us with details as to when and where will the next 2011 SOLACI Congress take place?

It will take place in Santiago de Chile at the Casapiedra Convention Center from Wednesday August 3rd to Friday August 5th.

- SOLACI has not held its Congress in Chile for quite a while, what are the expectations?

Expectations are high since the Chilean interventional cardiology sector is very excited about showing the important developments that have taken place since SOLACI 1999. We want to be up to the task as regards the scientific quality the congress has had in recent years and, at the same time, we look forward to



meeting and having a deep, fruitful dialog with clinical cardiologists and our fellow surgeons.

- Our Congress Office allows us to maintain a certain level of consistency among events. How does its activity (Cont. Page 3)

TCT & SOLACI

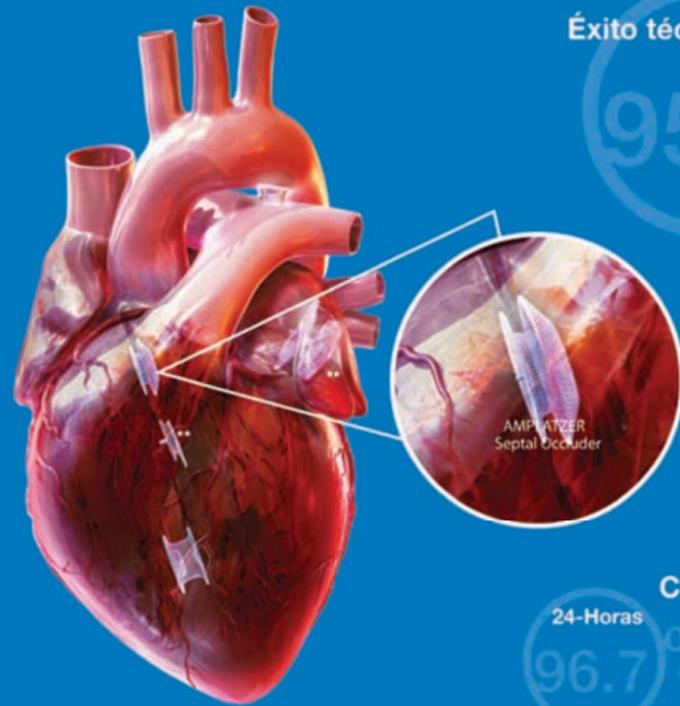


restenosis and coronary bifurcation lesions, as well as in artery femoral superficial lesions. Dr. Roxana Mehran addressed the topic of new platelet antiaggregants and the rational bases for their use, with special emphasis on the relationship between ischemic events reduction and increased bleeding. She also spoke about the use of some laboratory methods to measure the degree of platelet activity.

The Pacifico Conference Room hosted the TCT&SOLACI joint session coordinated by Dr. Gregg Stone. During this session, Dr. Juan Granada reviewed the current status of drug-eluting balloons, and their potential use for the treatment of intrastent

In this respect, she explained that so far there is no reason to add this laboratory study to daily practice. Dr. Stone then talked about the PROSPECT study and plaque vulnerability. Finally, Dr. Alexander Abizaid spoke about new developments in stents with special (Cont. Page 3)

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SOLACY DAILY

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(Cont. of "Interview with Dr. Dussallant")

...integrate with local activities, taking into account that the organization is based in Buenos Aires?

Internet is the key, since it allows us to stay in permanent contact through email, Skype and other tools that help us establish teleconferences, exchange files, etc. quickly and at a low cost. Likewise, Chilean companies are updated in that regard and their web pages are very informative and their work styles include the use of these technologies. Besides, the Chilean Cardiology and Cardiovascular Surgery Society support the organization of this kind of events with its broad local experience.

- How important is it for Chile to host a congress of this nature?

First of all, it is the recognition of the Chilean interventional cardiology by SOLACI authorities and an excellent opportunity to show part of what we are doing in this area in the country, to our Latin American colleagues as well as to other specialists.

- Do you think the number of foreign guest must be reduced in order to harmonize the program?

We may have fewer guests than we had in Buenos Aires or Rio de Janeiro, but a greater level of involvement by those guests will allow maintaining the usual quality standards of SOLACI Congresses.

- Regarding scientific issues, which are the main subjects to be dealt with? Will other specialists have major involvement?

The list of topics will cover different interventional cardiology areas with emphasis on rapidly-developing areas such as aortic valve prosthesis implantation or pharmacoactive stents, but without neglecting other topics. We want to foster a higher level of involvement by clinical cardiologists.

- What do you think about the idea of publishing a congress journal and this first experience with SOLACI DAILY?

It is an excellent idea that has been successful in Chilean and international congresses. It allows for fast broadcast and communication with attendants, and also it allows us to feel the "pulse" of the event.

- What is your analysis of Chilean interventional cardiology in comparison to its situation in the region and in the world?

I think what I said earlier is also true for Chile. Within the Latin American context, I think progress has been made in terms of the techniques and devices that have been incorporated, as well as in terms of population's access to diagnosis and invasive endovascular treatment.

- Is there anything else you would like to say to the attendants to SOLACI in Buenos Aires?

Be prepared to attend and become actively involved in SOLACI 2011 by sharing your experiences. Get ready to know and enjoy a different side of Santiago as well as the multiple attractions Chile has to offer as a travel destination. I think it will be an unforgettable experience from the scientific and social point of view. We are expecting you with open arms.

For inquiries, please contact congreso@solaci.org

(Cont. of "TCT & SOLACI")

...emphasis on polymers and biodegradable platforms, and polymer-free stents.

The session included the transmission of live procedures, which consisted in endovascular treatment of coronary lesions in two main coronary artery bifurcations and one right coronary artery bifurcation, with an interesting debate about the use of different techniques to improve long-term results.

When crossing is key to procedural success: outback® Ltd™ re- entry catheter

By Dr. Oscar Mendiz

Chronic total occlusions (CTOs) of lower extremity arteries are a common occurrence in patients who are diagnosed with peripheral arterial disease. Although bypass surgery has been the traditional recommendation for the treatment of TASC II type C and D lesions, endovascular is gaining ground at a fast pace. There have been strong advances in the endovascular interventions and a wide array of devices and approaches have been developed as means to achieve the arterial perfusion to the lower extremity. Although most CTOs are usually crossed with the use of conventional wires, in many cases it can become a time-consuming effort and most likely will follow the pattern of a 20% failure rate due mostly to the inability to wire the true lumen and cross the occlusion.

Percutaneous Intentional Extraluminal Recanalisation (PIER) was introduced by Bolla in 1989 and can be used in lesions typically difficult to treat with intraluminal percutaneous transluminal angioplasty including long chronic occlusions, diffuse tandem occlusions and calcified occlusions. The use of the PIER

technique when treating limb ischemia is comparable to arterial bypass when stents are used afterwards to improve patency. When the wire is subintimal at the site of vessel reconstitution, and the PIER technique cannot be completed successfully, the Outback® LTD™ re-entry catheter becomes a handy tool that allows for a quick and safe access to the true lumen. The result leads to a successful outcome for the patient, which would have otherwise been sent to surgery for bypass or amputation.

The Outback® LTD™ re-entry catheter is 6F compatible and intended to facilitate guidewire placement in select regions of the peripheral vasculature (excluding cerebral and carotid). It follows three simple steps (LOCATE, TUNE AND DEPLOY) which are performed under standard fluoroscopy. The Outback® LTD™ is advanced over a .014" guidewire into the subintimal space until its tip is adjacent to the true lumen of the artery. The orientation of the inside needle is confirmed through angiographic views and once placed correctly, a button is pressed to release a needle that punctures the intima under fluoroscopic control. Through this recently opened channel, the 0.014" guidewire is advanced into the true lumen passing the reconstitution point of the vessel. After this, the Outback® LTD™ re-entry catheter is withdrawn and exchanged for the PTA balloon of choice for dilation and stenting.

We have introduced the Outback® LTD™ to the practice of our staff since last year with great success. It has allowed us to face patients that we simply gave up on before and nowadays we are utilizing the device in more than 50% of the CTOs. We are even starting with the subintimal approach in most of the SFA cases where we find a long occlusion knowing that we may end up using the Outback® LTD™. In conclusion, the device can be used with accuracy and safety, increasing possibilities of procedural success. It is true that Lower Extremity occlusions remain a challenge, but the Outback® LTD™ re-entry catheter proves significant progress in the advancement towards more severe and extensive occlusions under the endovascular approach.

Friday Schedule 13/08

Friday August 13th	01. Pacific	02. Atlantic	03. Buenos Aires A+B	04. Buenos Aires C Nurses & Technicians	06. Pacara (Congenital & Structural Heart Disease)
08:00 - 09:00	Clinical Assessment of Valvular Patients	Pediatric Live Cases (8:00-9:30)	Abstracts Session IV	Burn Out Syndrome	
09:00 - 10:30	Live Cases	Acute Coronary Syndromes		Complications in Interventional Cardiology	Percutaneous Treatment of Aortic Coarctation (9:30 - 11:00)
10:30 - 12:00	Percutaneous Treatment of Aortic Stenosis. Live Case	Revascularization Strategy for Patients with Left Main and CTO		Interventional Cardiology	
12:00 - 13:30	Antiplatelet Therapy in ACS and PCI (Lunch Symposium Sponsored by Eli Lilly)	Live Cases	GP IIb/IIIa Inhibitors (Lunch Symposium Sponsored by Celofarm & Biotoscana)		Key-Note Lecture (11:30 - 12:15) - ASD, VSD and PDA (12:30 - 14:30)
14:00 - 15:30	Best Abstracts Awards	Interventions for Clinical Cardiologists VI	Images in Interventional Cardiology III		
15:30 - 16:00	Closing Lecture & Ceremony (R Virmani: Stent Selection in Vulnerable Plaque)	Best Pediatric Abstracts (14:30-15:30)			

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ENDURANT® in real world AAA patients: ENGAGE global study celebrates completion of 700 enrollments

By Tony Semedo

Medtronic Cardiovascular is excited to announce that ENGAGE, the post market clinical study of Medtronic's latest-generation device, Endurant®, has reached a significant milestone this month. A little over a year since its beginning, ENGAGE has crossed 700 enrollments. Significantly ahead of the schedule, ENGAGE is well on its way to complete 1200 implants worldwide. The 700th implant was done at the Epworth Hospital in Melbourne by Prof. Michael Grigg on 23rd June 2010.

Unprecedented in size and scope, ENGAGE aims to expand the clinical knowledge base by generating clinical data with real-world Endurant® patients. ENGAGE will enroll 1200 patients at up to 80 sites spanning six continents. The follow-up period will be five years.

ENGAGE demonstrates Medtronic's commitment to the pursuit of evidence-based medicine and exemplifies Medtronic's confidence in the real-world application of the Endurant® stent graft system. Endurant®, Medtronic's lead-

ing AAA stent graft, is designed with evolutionary precision for accurate placement in straightforward and challenging anatomies, to which it adapts extremely well due to a highly flexible and conformable body. The device has been widely adopted by endovascular specialists worldwide and recently completed 15,000 commercial implants globally since its launch in 2008. This feat underscores how quickly Endurant® has changed the lives of many patients and how it is leading the frontiers of the EVAR therapy.

The endovascular community's confidence in the Endurant® device is also reflected in the astounding rate at which ENGAGE is progressing. Valuable clinical insights supporting



Tony Semedo

Endurant®'s clinical effectiveness are starting to become available from ENGAGE. Prof. Dittmar Boeckler, an ENGAGE executive committee member, presented the follow-up data for 180 patients at Charing Cross 2010. "As an ENGAGE Executive Committee member, it is my pleasure to present to the clinical community the first set of data emanating from ENGAGE," said Prof. Dittmar Boeckler of

Center University Clinic Heidelberg, Germany. "ENGAGE is a ground-breaking study and by generating meaningful clinical evidence, it will enable the clinical community to further the advances in EVAR with confidence."

The ENGAGE enrollment began 2009 March at Queen Elizabeth Hospital in Adelaide, Australia

when Dr. Rob Fitzridge treated a patient using the Endurant® Stent Graft System. Since then, 67 sites have been activated worldwide and all the sites are expected to be active by July 2010. "We are excited about the amazing progress this study has made in little over a year, something symbolic of the endovascular community's excitement towards the Endurant® Stent Graft System," said Tony Semedo, vice president of Medtronic Cardiovascular and general manager of Medtronic's Endovascular Innovations business. "We would like to thank all the participating sites for their enthusiasm and the executive committee for their insightful leadership that made this achievement possible."

Clinical safety and performance data on the Endurant® Stent Graft System have also been collected recently during the European market trial. Charing Cross 2010 also saw Prof. Hence Verhagen, Principal Investigator, present the 1-year follow-up data from the Endurant EU trial. Dr. Michel Makaroun, Principal Investigator, presented the US IDE clinical trial data at the late-breaking trial session at the SVS's Vascular Annual Meeting in June.

Is there such thing as a "DES class effect"?

By Dr. Daniel Berrocal

Much has been written in an attempt to compare the results of the Paclitaxel-eluting stent with limus-eluting stents. However it has seemingly been assumed that all these limus-eluting stents belong to the same group or are identical, with similar results. This literature interpretation phenomenon, known in pharmacology as "class effect", is not applicable to devices such as stents, and assuming this would imply making a very serious mistake. There are clear differences in terms of platform, polymer, elution curves, etc. Moreover, clinical studies also show a broad array of results in terms of both efficacy and safety.

During the Symposium several speakers referred to a tentative grouping of drug-eluting stents:

1. Group of stents without (or with very few) clinical studies with their results disclosed: unfortunately many DES belong to this group; since data about their safety and efficacy are unknown, it is impossible to make a comparative analysis simply because there is not enough information to do so.
2. Group of stents with inadequate clinical results: in the light of clinical results, some limus-eluting DES have been recalled because they failed to achieve the expected results. The Zotarolimus-eluting stent Zomaxx could

be an example of this group. Furthermore, the Costar stent would be an example of a similar Paclitaxel-eluting stent. These stents are a clear example that the results achieved by a DES are not just due to the drug, but to the interaction of its complex structure formed by the platform, the polymer and the drug, including total dose and elution curve.

3. Group of stents with strong clinical evidence that have become standard practice: this group includes a variety of DES with very different features, since they all elute different drugs, and we cannot ignore the impact that their platforms and polymers can have on immediate and remote results.

It is therefore important not to extrapolate the results of one DES to another simply because they have the same drug, without paying attention to the differences in their structure and especially the supporting literature.

It was pointed out that, within the group of limus-eluting stents, the Cypher stent has the most clinical studies with excellent results in terms of safety and efficacy. As a first generation DES, however, it has the most rudimentary platform with the thickest strut (140 µm), making it stiffer and therefore less deliverable or capable of accessing complex lesions, which might limit its use in some cases. The Endeavor stent has a thin strut platform, offering a clear deliverability advantage; however, given the characteristics of its polymer, it delivers almost

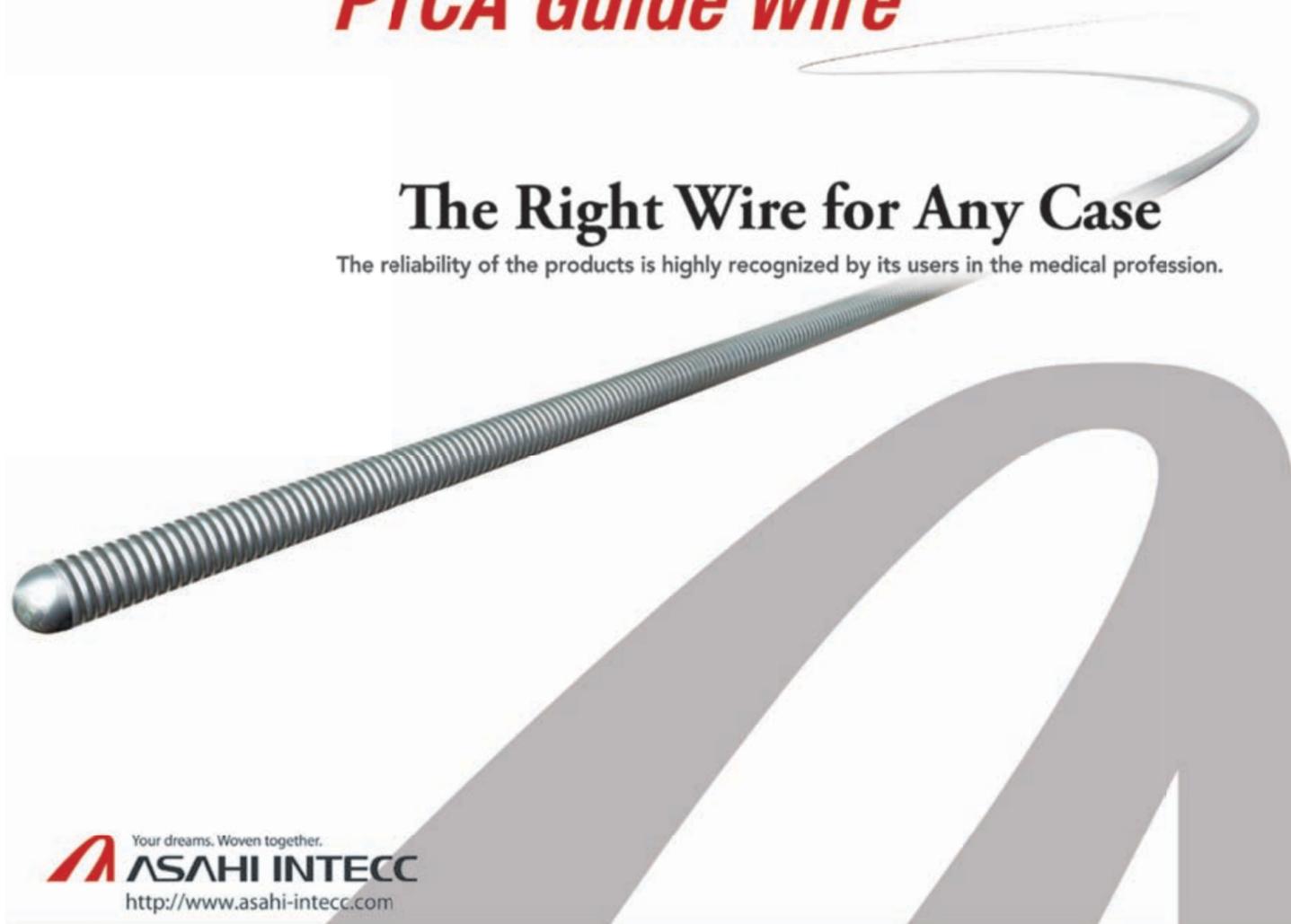
all the Zotarolimus in the first two days after implanted, leaving most of the complex process that ends up in restenosis "uncovered". For this reason, as to its efficacy, in clinical studies this stent has shown to be less powerful than other olimus-eluting DES, and this is most evident in diabetic patients as shown in the SORTOUT III study and the SCAAR and WESTERN DENMARK registries. The Resolute stent arises from the change in the Endeavor stent polymer (maintaining the same platform and drug); thus, the problem with the Zotarolimus elution kinetics was solved, and the Resolute All-Comers study showed a significant improvement in the efficacy of this device. The BioMatrix stent has a polymer formed by two layers, an external aluminized coating made of bioabsorbable polymer and an internal permanent polymer (Parylene) layer which, as in the rest of permanent polymer DES, will remain around the stent metal after the implant. Possibly because this stent leaves a permanent polymer coating in contact with tissues, the LEADERS study results did not show any clinical benefits against the first generation DES Cypher. In turn, the Taxus stent elutes Paclitaxel, which has an antiproliferative and antimigratory action through a mechanism different from that of olimus drugs. Medium-term angiographic results seem to show this drug is less powerful than that in the Cypher (Sirolimus) and Xience v/Promus (Everolimus) stents; however, this di-

ference tends to disappear in the long term as shown by the remote 5-year follow-up results of the SIRTAX study and the 2-year follow up of the SPIRIT II study. These differences observed in the general population seem to reverse in the group of diabetic patients, where Paclitaxel maintains the same anti-restenotic power because of its mechanism of action. In several studies, the Xience v/Promus stent has proven to be one of the most powerful stents in terms of efficacy, and has shown safety benefits as well. However, this merely generates a hypothesis that will have to be tested through customized studies, since in no case was the n in the sample calculated for that purpose. Much attention should be paid to these issues in order to properly interpret the results of the studies. After a fruitful discussion everybody agreed on the vital importance to understand that all DES must be evaluated for their own results instead of the drug they elute. It is clear that within the group of DES eluting the same type of drug there is a universe of different results as a consequence of the other variables that make up a DES, beyond the drug, namely, the composition, design and behavior of each of its platforms. They concluded that from all points of view, it is wrong to consider that there is a "DES class effect"; assuming this fallacy might lead to failing to choose the right DES for patients.

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Drug-eluting stents new platforms: element

By Dr. Pablo Kantor

Since the emergence of Drug-Eluting Stents (DES), their platforms, polymers and drugs have changed in many ways. The first DESs that were introduced into the market had stainless-steel platforms. This alloy provided an excellent radial strength. In other words, very good resistance to external compression and minimal recoil, which means that once the stent had been expanded, it maintained the diameter to which it had been opened. By then, however, several clinical studies had shown that metal thickness of the stent was directly related to its clinical results in terms of incidence of restenosis, the smaller the thickness, the lower the restenosis rate. In this respect, stainless steel had a limitation, which was its scarce radio-opacity, which made the stent very difficult to see when its thickness was smaller. Therefore, there appeared new alloys, such as Cobalt-Chrome, with greater radio-opacity, which allowed for the reduction of the thickness of the stent, while maintaining its visibility. Its radial strength, however, was lower than that of stainless steel and stent recoil, higher. This made it necessary to continue searching for new and better alloys for stents. The new ELEMENT (platform) stent uses a Platinum-Chrome alloy, which due to its excellent radio-opacity it allows it to maintain one of the smallest metal thickness when compared to the rest of the stents in the market (81 µm), and even so maintaining excellent visibility. Therefore, "in-vitro" studies showed a higher radial strength of the ELEMENT stent in comparison with two Cobalt-Chrome stents and two of the most widely used stainless steel stents, and a lower strength in relation to Cobalt-Chrome stent. Multiple preclinical studies aimed at assessing the biocompatibility of this new stent were carried out in several animal models (the most

recently presented in the prestigious euroPCR Congress held this year), in which endothelialization rates and inflammation parameters were insignificant when compared to different stainless steel and Cobalt-Chrome stents currently in use. Nickel, a metal which is present in all stent alloys, has been isolated as a highly allergenic component that could cause inflammation and eventual restenosis, as shown by clinical studies. In this respect, it is worth noticing that the ELEMENT stent only contains 9% of Nickel, the lowest composition in relation to all the other stents, which in some cases reaches 35%. This new platform will be available with Paclitaxel (Taxus Element) and Everolimus (Promus Element) and will be supported by the comprehensive literature behind the Taxus stent and the Promus (Xience v) stent, together with protocols appropriately designed to validate and prove the feasibility of transferring the polymer and drug technology to a new platform. Studies which have already been presented and published, such as Perseus Workhorse and Perseus Small Vessel, comparing the Taxus Element stent vs. Taxus Express and Express (BMS) respectively, demonstrated the feasibility of transferring polymer/drug to the new Element platform. Protocols such as the Platinum, Platinum Small Vessel and Platinum Long Lesion will do the same with the Promus Element stent by comparing it to the Promus (Xience v) stent, whose preliminary results will be presented in next year TCT's Congress. The Platinum Plus study will compare "head to head" the two new generations of the Promus or Xience v stents: Promus Element vs. Xience Prime, reaffirming the need to support the new technology with clinical evidence. It is very interesting to observe the dynamics with which these stents are redesigned over and over again with the aim of improving their results for the benefit of our patients.

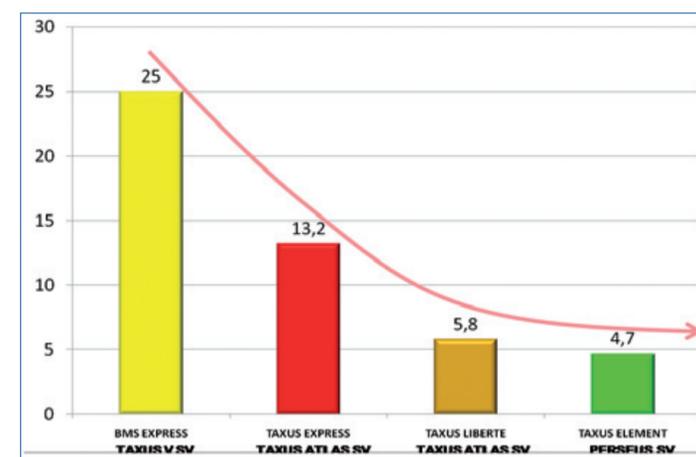


FIGURE 1: Need of target lesion revascularization (TLR) at 1 year in small vessels. Comparative results of multiple studies.

The ClearWay™ RX Local Therapeutic Infusion Catheter Cath Lab Digest talks with Rajesh M. Dave, MD, FACC, FSCAI

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

- How does this catheter work?

The ClearWay catheter is a microporous PTFE balloon, available in two different forms. One is a monorail .014"-compatible device primarily designed for use in the coronaries, although it can be used in the vasculature as well. The company also has another version, an .035"-compatible over-the-wire device. This device is FDA approved for any drug or diagnostic fluid. Essentially, a drug is injected through the balloon, which inflates as the drug is injected. Based on multiple publications and our clinical experience, glycoprotein (GP) IIb/IIIa inhibitors show the most promise, but nitroglycerin, sodium nitroprusside, tPA, retevas, and paclitaxel have all been utilized in different centers, based on the indication and the procedure.1

- How long does the drug actually stay at the site?

As the balloon inflates while you are injecting the drug, you actually slow down the coronary flow. The localized concentration of the drug is significantly higher and it remains at the site for a great deal longer than if you just injected a drug through the guide catheter, resulting in significantly increased drug residence time in the artery.

- How do you decide on the size of the catheter?

If you have a totally occluded artery or a tight lesion, we would recommend a 1.0mm x 20mm catheter, as it will produce the desired contact between the thrombus and device. I usually use a 1.0mm or 1.5mm diameter ClearWay catheter. In the lower extremities, I most frequently use a 2.0mm x 50mm device in the femoropopliteal segment and shorter catheters in below-the-knee distribution.

- How does the catheter fit into current treatment?

Ultimately, the ClearWay catheter is a new way of delivering site specific high concentrations of the drug, which is potentially more effective than just injecting through a sheath or through an end-hole catheter due to greater contact of the agent with the thrombus.

- What's your history with the ClearWay catheter?

We have done approximately 700 cases at our center with this catheter, utilizing it in many different circumstances, such as STEMI, NSTEMI, thrombus-containing lesions, vein

grafts, case complications such as no reflow/slow flow and distal embolization resolution, complex femoral popliteal occlusions, cases of critical limb ischemia, and also thrombus-containing lower-extremity lesions.

- You just completed a series on critical limb ischemia patients. Can you describe your experience?

Our analysis contained 70-plus patients with complex, multi-vessel disease. All of these patients had critical limb ischemia, with non-healing ulcers, gangrene, rest pain, and very complex lower extremity arterial disease. We used a vascular ClearWay catheter to inject Abciximab prior to an atherectomy procedure, which was the mainstay of therapy in the majority of these patients. What we have seen so far is that the likelihood of distal embolization was close to zero, in contrast to published distal embolization rates of anywhere from 7-10% in these types of cases. In addition, ClearWay catheter-treated patients had a significantly lower risk of reocclusion of these vessels at 6-month follow up. Flow in the pedal vessels was significantly improved, and because the distal embolization risk is so small, especially with the use of Abciximab, the likelihood of wound healing is going to be much greater, and the time to wound healing is going to be shorter. Due to better pedal arch flow, less distal embolization and less re-occlusions, we did see a much shorter time to wound healing in these patients.

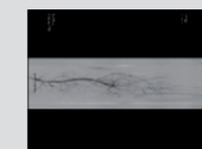


Figure 1. Patient with rest pain, prior endovascular treatment of popliteal artery with Gore Viabahn stent graft as well as nitinol bare metal stent, presents with occlusion of treated site.

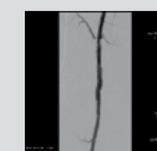
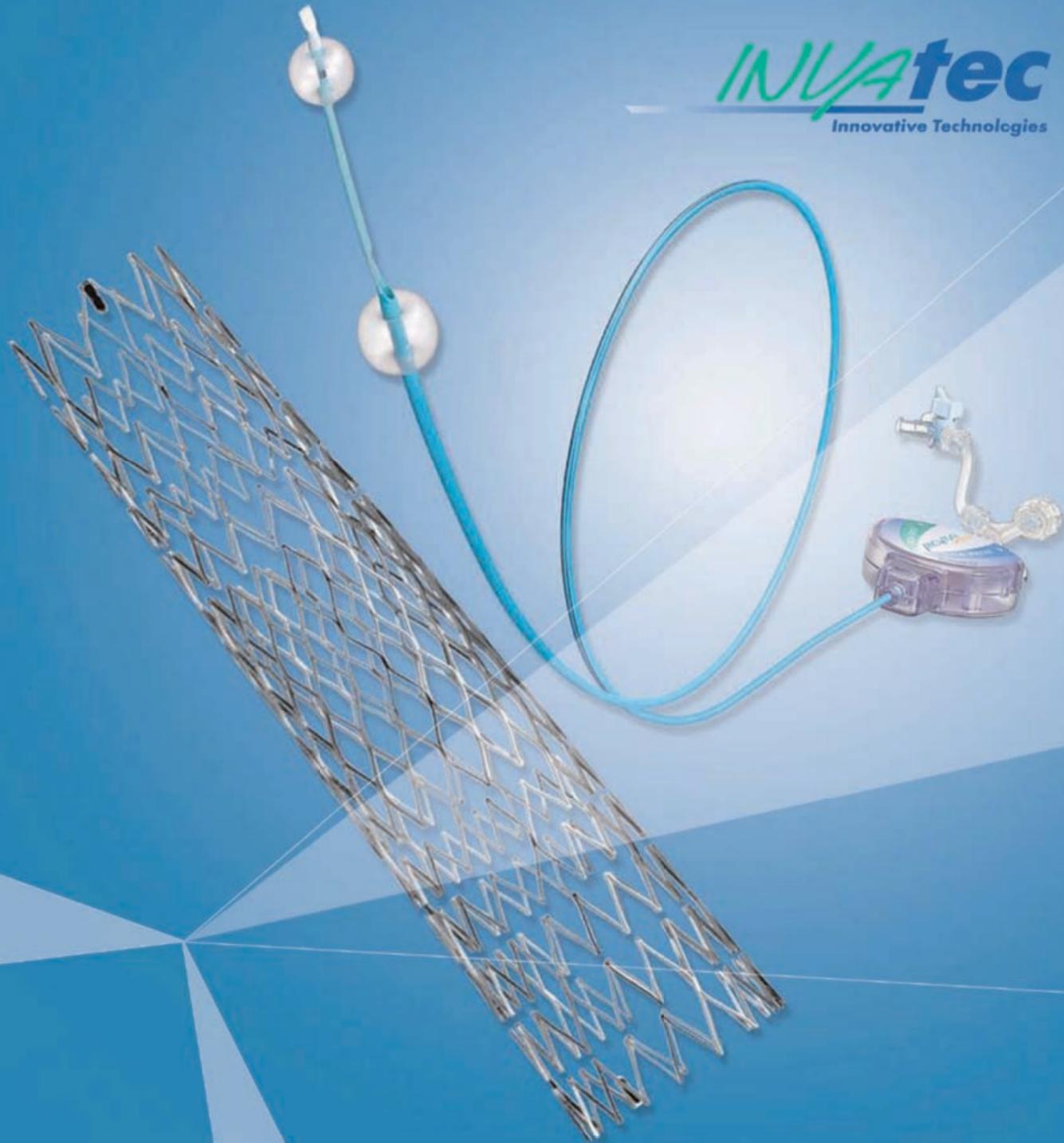


Figure 2. ClearWay Catheter with a weight adjusted bolus of ClearWay and Pathway Jetstream Atherectomy, final result without any new stents.



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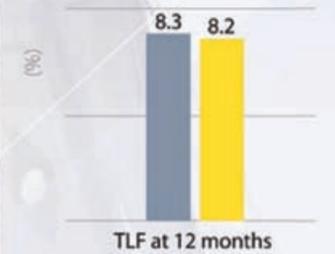
International Multicentre DES Clinical Trial

Resolute DES
matches Xience V DES

Primary Endpoint: TLF

Xience V DES (n = 1126)
Resolute DES (n = 1119)

$p_{noninferiority} < 0.001$



TLF at 12 months

TLF is the primary endpoint of the trial. It is defined as the composite of all-cause mortality, acute myocardial infarction, stroke, and target vessel revascularization.

Innovating for life.



Interview with professor Doctor Carlos Nicoli

Dr. Carlos Nicoli

Dr. Carlos Nicoli is Associate Professor of Ophthalmology at the University of Buenos Aires (Chairman of Ophthalmology at the Durand Hospital), Medical Director of Oftalmos Eye Institute, Former President of the Argentina Society of Ophthalmology and the Latin American Association of Cataract and Refractive Surgery.

RELID - Buenos Aires, is an observational study which aims to detect the presence of cataracts associated with radiation exposure in the settings of the congress. We had the opportunity to interview Professor Carlos Nicoli, one of the most relevant ophthalmologists in Argentina who is participating in the study.

SOLACI: - Professor, we know that your specialty is surgery of the anterior eye segment, among other structures including the lens, main objective of the RELID study evaluation. Could you explain why is so important for the interventional cardiologists to be evaluated?

CN: It is certainly important for his/her eye health, as he or she will have the possibility to have examined the lens of both eyes, by a highly trained professional. Using a noninvasi-

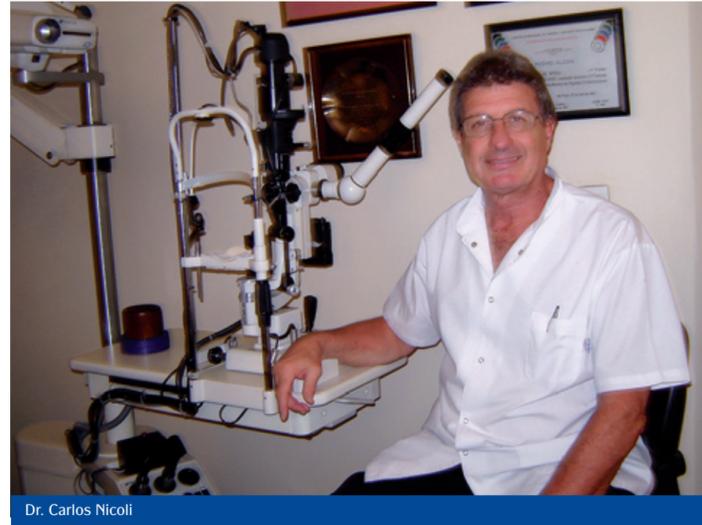
ve lighting system we will be able to detect the existence of early cataracts and to implement a prevention and monitoring behavior that will affect their future visual health.

SOLACI: What are the implications of this, for the community of cardiologists and medical assistants?

CN: It will be significant in two crucial aspects. The first one will be related to the future development and application of biosafety protocols by IAEA experts and authorities on the subject. The second, which specifically concerns my activity as ophthalmologist, is that we will be able to detect this type of lens opacities in early stages in the context of specifically designed protocols in this segment of the population.

SOLACI: - In the case of lens opacities being detected, what should be the next step?

CN: - In case we detect lens opacities it is important to analyze this feature in the context of a comprehensive ophthalmologic evaluation in order to evaluate in what extent this finding reduces visual accuracy. In most cases, we expect to find only very small lens opacities and the advice would be only to remain under observation; but if the progress of the cataract is resulting in a significant decrease of visual ac-



Dr. Carlos Nicoli

curacy, surgery and intraocular lens implantation should be advised.

SOLACI: - In your experience, what is the incidence of lens opacities related to radiation exposure?

CN: - Is not very high to date, but we must keep in mind that this is a relatively new specialty and the number of interventional cardiologists is increasing. To keep in mind this risk will help us to effectively prevent and reduce the frequency of cataracts in this specific community.

Importance of intracoronary ultrasound in the drug-eluting stent era

Intracoronary ultrasound (IVUS) has proven to be of major significance in guiding non-drug-eluting stent (non-DES) implant, reducing the clinical event rate mainly through a reduction in the clinical and angiographic restenosis rate. In the drug stent era, IVUS has shown its clinical significance for reducing drug-eluting stent thrombosis and mortality rates.

By Dr. Costantino Costantini

Intracoronary ultrasound (IVUS), allowing higher acute gain, significantly impacts on the clinical course of patients with implanted non-drug-eluting stents (non-DES), reducing the clinical and/or angiographic restenosis rates. Nowadays, since drug-eluting stents (DES) inhibit neointimal proliferation and consequently result in a lower restenosis rate, they are increasingly used in interventional practice.

Given DES great biological power, the interventional community overlooked the importance of the appropriate stent implant technique.

As a result, many adverse clinical events such as stent thrombosis and subsequent acute myocardial infarction, which could be reduced or prevented through an appropriate implant technique, led to DES being severely challenged as to their safety.

IVUS enables a more appropriate implant tech-

nique since it allows:

- Identification of the type of atherosclerotic plaque and the need for specific plaque preparation before stent implant (rotational atherectomy);

- A more accurate assessment of the size of the coronary vessel in order to select the most appropriate stent size;

- Identification of the proximal and distal reference segments with the lowest atherosclerotic plaque burden where to start and end the stent to be implanted and thus select the exact length of the stent to implant;

- Optimization of the final cross section after stent implant;

- Identification of complications that are not visible with angiography.

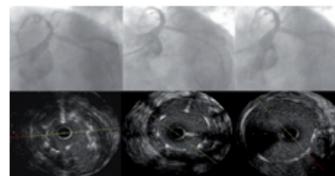
Initially, some studies of IVUS-guided DES-implant showed that a poor DES implant technique was directly related to complications in the patient's clinical course. Hypo-expansion and problems with DES edges were the main

predictors of thrombosis and of clinical and angiographic restenosis.

Although some studies have correlated the final luminal area with the clinical course of DES-implanted patients, these values between 5.0 mm² and 5.7 mm² cannot be extrapolated to all arteries and segments treated and should be used wisely. Some real world clinical studies have shown that the use of intracoronary ultrasound significantly reduces the DES thrombosis rate.

Although given its clinical benefits IVUS should be widely used, for reasons of economy it is often used for lesions and/or patients with increased risk of complications (long lesions, small vessels, need for multiple stents, bifurcations, diabetic patients).

However, the use of IVUS is mandatory in treating lesions located in the unprotected left coronary artery trunk. Dr. Park's group, the most experienced group in treating unprotected trunk lesions worldwide, showed that the

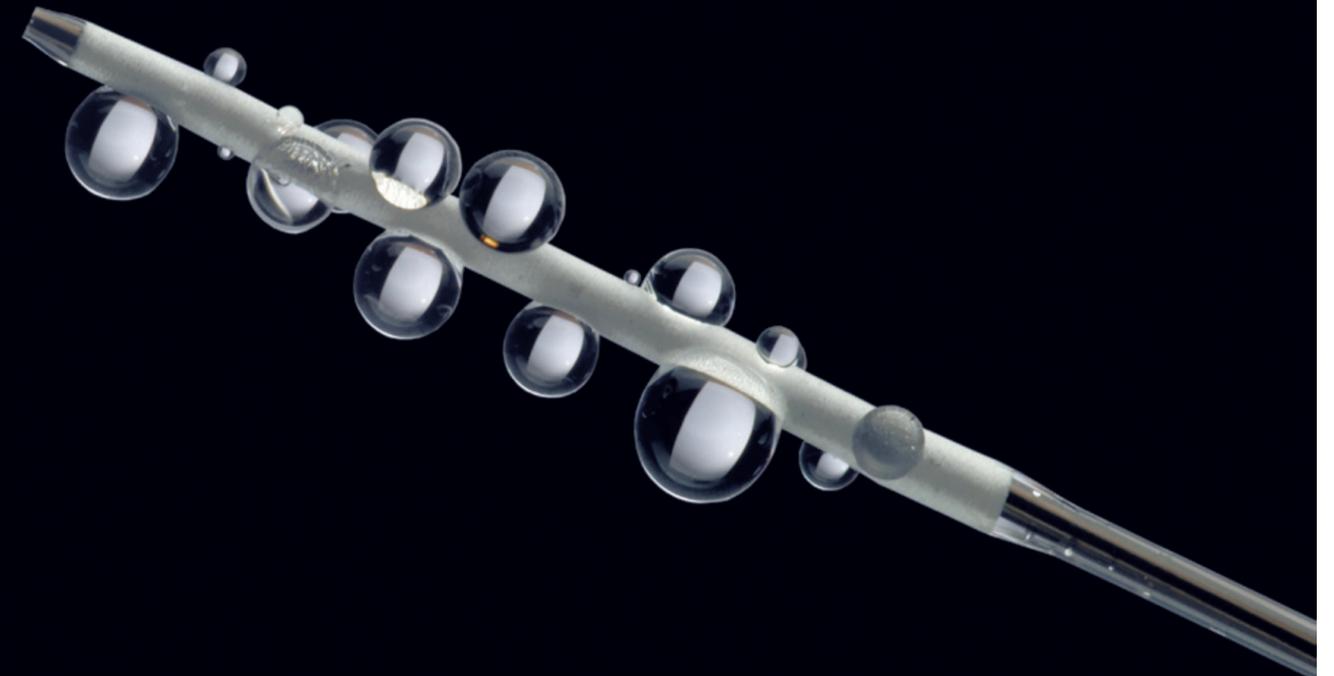


failure to use IVUS is a predictor of mortality in this group of patients.

Our patients' clinical course depends on several much more important factors than the type of DES used. It mainly depends on the stent having been properly implanted, thus reducing the possibility of complications to factors other than inappropriate implant.

Thus, IVUS is a very important tool in the interventional cardiologist's therapeutic arsenal. Though its use involves a learning curve, this curve is relatively short and directly related to frequency of use, which guarantees widespread use of this important technique.

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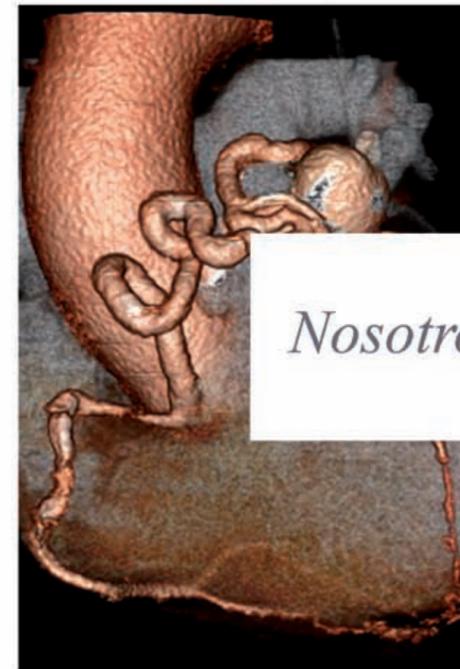
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* American Heart Association (2006). Heart disease and stroke statistics – 2006 update. Circulation. 113(8): e85–e151.
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Stent Selection in Vulnerable Plaque

By Renu Virmani, M.D., Masataka Nakano, M.D., Fumiyuki Otsuka, M.D., and Alok V. Finn, M.D.*

Recently much progress has been made in the understanding of vulnerable plaque (VP). Most of this understanding has come from autopsy studies and more recently from higher resolution intravascular technologies for the identification of such lesions in vivo. Here we will discuss not only morphology of vulnerable plaque/ruptured plaque but also address the issue of which stents may be more appropriate for the treatment of vulnerable plaque.

Vulnerable plaque/Thin-cap Fibroatheroma
Coronary lesions that morphologically resemble ruptured plaque have been designated by our laboratory as thin-cap fibroatheromas (TCFA). The morphology of the TCFA shows a relatively large necrotic core with an overlying thin intact fibrous cap infiltrated by macrophages (Figure 1). The fibrous cap thickness as a measure of plaque vulnerability is defined as ≤ 65 microns since mean measurement of the thinnest portion of the remnant ruptured cap was 23 ± 19 μm , with 95% of the caps measuring < 65 μm .

Healed plaque rupture
Morphologic studies suggest that plaque progression beyond 40 to 50 % cross-sectional-area luminal narrowing occurs secondary to repeated silent ruptures. (Figure 1) Davies showed that the frequency of healed plaque rupture (HPR) increases along with lumen narrowing. In our laboratory, 61% of hearts from sudden coronary death victims showed HRP. The prevalence of silent ruptures in the clinical setting remains unknown to date.

Can we predict which VP is most likely to rupture?

The degree of luminal narrowing does not predict the extent of underlying plaque instability. In detailed morphometric analysis of ruptured plaques, 80% of necrotic cores were larger than 1.0 mm² while only 60% of TCFA had similar extent of necrotic core. In an effort to better understand indices of plaque vulnerability from an imaging perspective, a histopathologic analysis was performed on atherosclerotic plaques with mild stenosis of 50-75% cross-sectional luminal narrowing collected at autopsy from sudden coronary death victims. A multivariate logistic regression analysis reveals that the best independent predictors of the likelihood for plaque rupture was cap thickness, followed by % necrotic core area, in addition % area of macrophage infiltration. These data should be applied to target current imaging modalities for the prediction of plaque progression and its vulnerability along with positive remodeling.

How do we Treat Vulnerable Plaques that are Non-Critically Narrowed?

The PROSPECT trial has shown that lesions identified as vulnerable plaques by Virtual Histology (VH)-IVUS showed a higher incidence of target lesion revascularization (11.6%) within 3.4 years, and were angiographically mild. Therefore, it is important for us to know how to treat such lesions that will be identified by newly developing imaging devices targeting insignificantly narrowed lesions but have a VP-TCFA morphology. Currently, there are no studies to prove that treating such lesions, i.e. vulnerable plaques not severely narrowed, by PCI reduces mortality and morbidity. Until such studies are available we have no choice

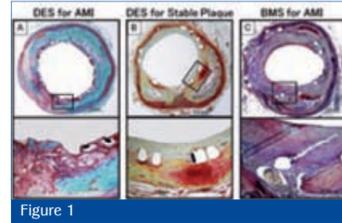


Figure 1

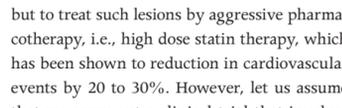


Figure 2

but to treat such lesions by aggressive pharmacotherapy, i.e., high dose statin therapy, which has been shown to reduction in cardiovascular events by 20 to 30%. However, let us assume that we carry out a clinical trial that involves treatment with PCI, our knowledge of current randomized trials does not give us clear signals if drug-eluting stents (DES) or bare metal stent (BMS) are the logical choice, let alone self-expanding stents.

We know from randomized clinical trials that for the first year DES have a lower rate of major adverse coronary events (MACE) than BMS while Daemen et al. showed that DES have a higher rate of late stent thrombosis (LST) and that this occurs more frequently in those with acute myocardial infarction. Also, Steg et al. showed that patients receiving DES or BMS for STEMI demonstrate increase late mortality for DES vs. BMS. Similarly, we have also shown that in patients in whom DES were deployed for AMI or TCFA there is a higher incidence of LST versus those receiving DES for stable lesions. (Figure 2)

So now the question arises, When DES is not the optimal choice, then are balloon expandable BMS better than self-expanding stents? The answers are not simple as we have little experience with self-expanding stents. One of

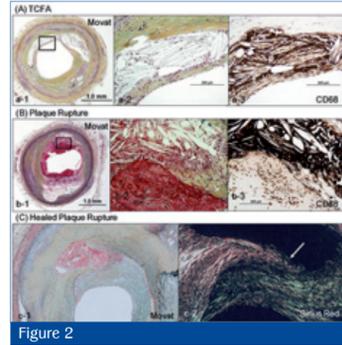


Figure 2

the options for treating VP is balloon expandable BMS however, this will lead to prolapse of necrotic core into the lumen and sub-acute thrombosis within 30-days even if the fibrous cap of VP isn't ruptured prior to stenting. Alternatively, self-expanding nitinol stents may be one of the wisest choices, provided it expands gradually and does not have a high expansion force.

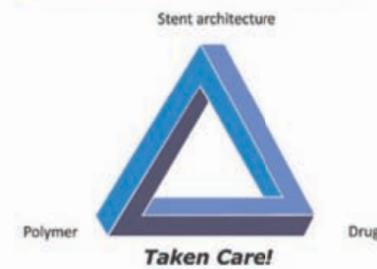
In the end

Before we can advocate interventional treatment for the VP, we need data about how to correctly diagnose one in vivo and secondly that treatment of these lesions would actually decrease cardiac morbidity and mortality. If we are to make progress, it will require a strict monetary commitment which seems a tall order in an era of shrinking research and healthcare budgets.

*From CVPPath Institute, Inc. (RV, MN, FO), Gaithersburg, MD; Emory University School of Medicine (AVF), Atlanta, GA.



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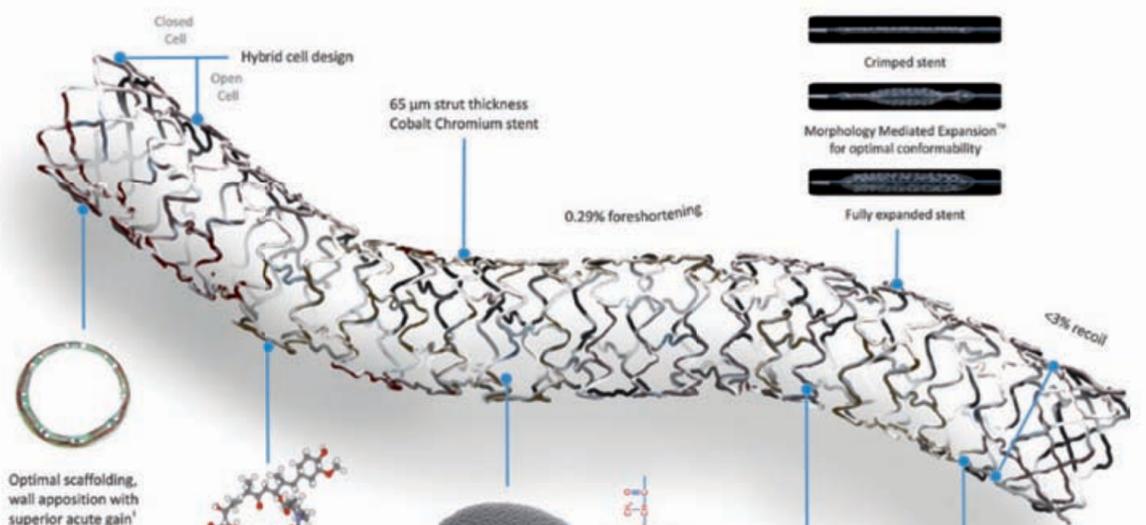


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1. Data on file. 2. Dr. Sameer Dani, IndiaJae 2010, New Delhi, India, Feb 2010.

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