24th CARDIOVASCULAR SUMMIT **TCTAP2019 Daily News**

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Spotlights of Major Clinical Studies with Expert Commentary



Gregg W. Stone, MD Columbia University Medical Center, USA

Deep Dive into MitraClip Trials for Functional MR

The mitral valve is a complex structure encompassing the valve leaflets, annulus, chordae tendineae, and papillary muscles. Current guidelines recommend early surgery for severe primary mitral regurgitation, but the management of secondary mitral regurgitation, which is essentially a disease of the left ventricle, is more controversial. Current guideline-directed medical therapy targeting the diseased left ventricle and cardiac resynchronization therapy can reduce the severity of secondary mitral regurgitation and are currently the only severe secondary mitral regurgitation were randomly assigned to either transcatheter repair plus medical therapy or medical therapy alone in the MITRA-FR trial (Percutaneous Repair with the MitraClip Device for Severe Functional/Secondary Mitral Regurgitation) and COAPT trial (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation). A total of 610 patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy were enrolled. After two years, there were 160 total heart failure hospitalizations among those who received the MitraClip versus 283 for the control group. The annualized rate of all hospitalizations for heart failure within 24 months was 35.8% per patient-year in the device group as compared with 67.9% per patient-year in the control group (hazard ratio [HR] 0.53; 95% confidence interval [CI] 0.40 to 0.70; p<0.001) (Figure 1)

The rate of

freedom from

device related

complications

at 12 months

was 96.6%

(lower 95%

confidence

limit, 94.8%;

p<0.001 for

comparison

performance

goal). Death

cause within 24 months occurred in

29.1% of the

with the

from anv



Figure 1. COAPT trial: All hospitalizations for heart failure within 24 months

management strategies with a class I recommendation.

Symptomatic patients with left ventricular systolic dysfunction and at least moderately

patients in the device group as compared with 46.1% in the control group (HR 0.62; 95% CI 0.46 to 0.82; p<0.001). The MITRA-FR trial showed no significant difference between the trial group with respect to the rate of death from any cause or unplanned hospitalization for heart failure at 1 year. The COAPT trial showed a significantly lower rate of hospitalization for heart failure at 2 years and significantly lower all-cause mortality at 2 years in the device group. Differences in patient characteristics, baseline valvular and ventricular characteristics, and procedural performance could be possible explanations for the differences in outcomes.

Management of left ventricular dysfunction with guideline-directed medical therapy and, when indicated, biventricular pacing, should be pursued before any intervention involving the mitral valve is considered. Among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone.

Spotlights of Major Clinical Studies with Expert Commentary

» Monday, April 29, 8:30 AM - 9:45 AM
 » Presentation Theater 1, Level 1

Tuesday, April 30, 2019

Today's Highlights

Master the CTO 2019 8:30 AM - 6:00 PM Coronary Theater. Level 1

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Structural Heart Disease Symposium 8:30 AM - 12:30 PM Structural Heart & En<u>dovascular Theater, Level 1</u>

> **Endovascular Symposium** 2:00 PM - 6:00 PM Structural Heart & Endovascular Theater, <u>Level 1</u>

Challenging Case Competition with Experts' Focus Review 8:30 AM - 12:20 PM Presentation Theater 1, Level 1

> Satellite Symposium: Morning Roundtable Forum 7:00 AM - 8:10 AM*

> > Lunchtime Activities 12:45 PM - 1:45 PM*

^{*} For details on the locations, please check TCTAP 2019 App





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General Information

Shuttle Bus

Free shuttle bus will run between COEX and several hotels Visit the **CVRF Booth** for more information.

Certificate of Attendance

Certificate of Attendance for TCTAP 2019 will be distributed along with the badge.

Cyber Station / Free Mobile Recharge

 CVRF Booth, Grand Ballroom Lobby, Level 1

• Lounge, Exhibition (B2) Hall, Level 1 · Lounge next to Registration Booth, Exhibition (B2) Hall Lobby, Level 1

Registration / Lost and Found / Coat Room

 Opening Hours: 8:30 AM - 6:30 PM, Saturday, April 27 6:00 AM - 6:00 PM, Sunday, April 28 -Tuesday, April 30

• Registration Booth, Exhibition (B2) Hall Lobby, Level 1

Tour Information

• Grand Ballroom Lobby, Level 1

 Tour information will be provided by COSMO JIN Tour and Korea Tourism Organization.

TCTAP 2019 TRAINING CENTER OPEN!

Training Center, Opposite of the Registration, Level 1

000000	Place	Time
Bifurcation Stenting Seminar 1 with Terumo	Training Center 3	4:00 PM - 5:30
SUNDAY, APRIL 28		
Session	Place	Time
Advanced TAVR with Edwards	Training Center 1	2:00 PM - 3:30
Renal Denervation & TAVR with Medtronic	Training Center 2	2:00 PM - 3:30
Bifurcation Stenting Seminar 2 with Terumo	Training Center 3	2:00 PM - 3:30
Antegrade Dissection and Re-Entry (ADR) with Boston Scientific	CTO Training Center	2:30 PM - 3:30
Bifurcation Stenting Seminar 3 with Terumo	Training Center 3	4:00 PM - 5:30

• Location : Exhibition & Training Center Booth, Registration (B2 Hall Lobby, Level1, COEX)

Onsite Registration

April 27(Sat), 2019 | 8:30 AM ~ 6:30 PM

April 28(Sun), 2019 ~ April 29(Mon), 2019 | 6:00 AM ~ 6:00 PM

Running Hour

Google play

Webcast & VOD

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Program

24th TCTAP

P

ain Arena

Meeting at a Glance

Session	Place	Time
Above the Call of Duty - PCI Optimization with OCT (Abbott)	Training Center 2	9:00 AM - 10:30 AM
Basic TAVR with Edwards	Training Center 1	10:00 AM - 11:30 AM
CTO Training Course: Lectures	CTO Training Center	10:30 AM - 12:10 PM
Angiojet (Pharmaco-Mechanical Thrombectomy) with Boston Scientific	Training Center 2	11:00 AM - 12:00 PM
Renal Denervation & Primary Prevention with Medtronic	Training Center 1	2:00 PM - 3:00 PM
Peripheral Intervention with Abbott	Training Center 2	2:00 PM - 3:30 PM
Bifurcation Stenting Seminar 4 with Terumo	Training Center 3	2:00 PM - 3:30 PM
CTO Training Course: CTO Hands-on Training	CTO Training Center	2:00 PM - 5:00 PM

	07:30	
	08:00	
	08:30	
Mas	09:00	
Opening	09:30	
Let	10:00	
×	10:30	
	11:00	
Mas	11:30	
Live	12:00	
	12:30	
ADC.	13:00	
Are	13:30	
	14:00	
Mas Live Case	14:30	
	15:00	
	15:30	
	16:00	
Mas	16:30	
Live Case	17:00	
	17:30	
	18:00	







- 4:00 PM 5:00 PM @ Structural Heart & Endovascular Theater, Level 1

07:00

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and more photos www.facebook.com/SummitTCTAP



Program at a Glance



Live Case Transmission from World-Renowned Medical Centers

Columbia University Medical Center, New York, USA

• 8:35 AM - 11:20 AM @ CTO Theater, Level 1

Operator(s): Dimitrios Karmpaliotis, Aiav J. Kirtane

Asan Medical Center, Seoul, Korea

- 8:35 AM 11:20 AM @ CTO Theater, Level 1
- Operator(s): (Case #1) Seung-Whan Lee, Chang Hoon Lee
 - (Case #2) Gerald Werner, Jong-Young Lee
- Imaging Interpreter: Do-Yoon Kang
- 10:20 AM 11:30 AM @ Structural Heart & Endovascular Theater, Level 1
- Operator(s): (Case #1) Horst Sievert, Jung-Min Ahn, Hojin Kim (Case #2) Duk-Woo Park, Vinayak Bapat, Euihong Ko
- Echo Interpreter: Dae-Hee Kim
- 11:20 AM 12:30 AM @ CTO Theater, Level 1
- Operator(s): (Case #3) Seung-Whan Lee, Jon Suh (Case #4) Paul Hsien-Li Kao, Gyung-Min Park
- Imaging Interpreter: Do-Yoon Kang
- 2:05 PM 3:00 PM @ Structural Heart & Endovascular Theater, Level 1
- Operator(s): (Case #1) Robert Bersin, Pil Hyung Lee
 - (Case #2) Young-Guk Ko, Chang Hoon Lee
- Operator(s): (Case #3) Jae-Hwan Lee, Cheol Hyun Lee
 - (Case #4) Osamu lida, Su Hong Kim



St. Paul Hospital, Vancouver, Canada

- 8:35 AM 10:20 AM @ Structural Heart & Endovascular Theater, Level 1
- Operator(s): (Case #1) Anson Cheung
- Operator(s): (Case #2) David Wood, John Graydon Webb



Severance Hospital, Seoul, Korea

- 11:30 AM 12:30 PM @ Structural Heart & Endovascular Theater, Level 1
- Operator(s): Myeong-Ki Hong, Young-Guk Ko
- Echo Interpreter: Geu Ru Hong
- 2:00 PM 4:00 PM @ CTO Theater, Level 1
- Operator(s): (Case #5) Byeong-Keuk Kim, Hoyoun Won (Case #6) Kenya Nasu, Jung-Hee Lee
- Imaging Interpreter: Jung Ho Heo
- CT Interpreter: Sanghoon Shin
- 4:00 PM 6:00 PM @ CTO Theater, Level 1
- Operator(s): (Case #7) Kambis Mashayekhi, Sung-Jin Hong (Case #8) Toshiya Muramatsu, Chul-Min Ahn
- CT Interpreter: Sanghoon Shin

4-5 **24th cardiovascular summit TCTAP2019 Daily News**

TCTAP 2019 Featured Clinical Research from Abstracts



Wei-Svun Hu, MD China Medical University Hospital.

A Novel Atrial Fibrillation Prediction Model for Asian Subjects - A Nationwide Cohort Study

There are several atrial fibrillation (AF) risk prediction models and some of them have been applied to Asian populations after calibration for the different risk factors but none have been tested with a firm methodology. Moreover, the predictive power of the models was modest Dr. Wei-Syun Hu at China Medical University Hospital, Taiwan, announced a new predictive model for AF risk using a large national database from Taiwan yesterday.



Upendra Kaul, MD Batra Hospital & Medical Research Centre.

weighted average F1, precision, and recall values were adopted to measure the prediction model performance and were calculated across the training set, test set, and all data. The area under receiving operating characteristic (ROC) curve was also presented to evaluate the performance of the prediction model.

Dr. Hu's prediction model achieved a k-fold crossvalidation accuracy of 0.972 (k=10). In the test set, the prediction achieved an F1 value of 0.968, precision value of 0.958, and recall value of 0.979. The area under the ROC curve of the model was 0.943 (95% confidence interval, 0.943-0.944) (Figure 1).

Tetrilimus everolimus-eluting stents (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) is a new stent which has ultra-thin strut (60 μ m) and biodegradable-polymer coating. Recently, the EVER-OCT study was published by Dr. Kaul and colleagues at Batra Hospital & Medical Research Centre, India. This study was to evaluate the safety and efficacy profiles of this new stent by means of serial optical coherence tomography (OCT) analysis, which confirms the degree of strut coverage, malapposition, and vessel wall response after stent implantation.

This study was a prospective, multi-center, single-





Figure 1. Receiver operating characteristic of random forest model

His retrospective study included almost 7,000,000 Asian subjects and used a random forest model methodology to make the findings more meaningful and to increase transparency in reporting. 20 features such as subjects' age, gender, underlying diseases, and CHA2DS2-VASc score in each 682,237 subjects with or without AF, were used to evaluate the fit to the model. The data was split into training and test sets at an approximately 9:1 ratio; 614,013 data points were placed into the training set and 68,224 data points were placed into the test set. The

"This study shows a novel AF risk prediction scheme for Asian individuals with a random forest model technique," said Dr. Hu. He also added that as it is based on a large longitudinal cohort and presents results from a cultural background, the outcomes are relevant, considering the relevant burden of AF and associated adverse events in terms of health and social costs, which goes beyond earlier findings. Moreover, he commented that the large database and novel statistical

approach will definitely strengthen the current research.

Evaluation of Vascular Response and Healing After Implantation of Tetrilimus **Everolimus-eluting Coronary Stent by Optical Coherence Tomography (EVER-OCT):** 3- and 6-Month Serial Analysis

arm, and investigator-initiated study performed at seven different sites in India between January 2017 and September 2018. In 57 patients who underwent implantation with \geq 1 Tetrilimus stent, OCT evaluations were performed. First 14 patients had follow-up OCT evaluation at 3 months and remaining 43 patients were examined at 6 months. Primary outcome measures included the degree of strut coverage and malapposition and thickness of neointimal hyperplasia (NIH) over covered struts.

In this study, a total 61 Tetrilimus stents were implanted to treat 59 lesions in 57 patients. OCT data were available for 14 patients (6,180 struts) at 3-month follow-up and for 30 patients (15,354 struts) at 6-month follow-up. At 3-month follow-up, rapid early healing was indicated by a high percentage (95.2%) of covered struts per lesion with very low (100 \pm 60 μ m) NIH accumulation over covered struts. The high antiproliferative efficacy profile was confirmed by low NIH area $(0.84 \pm 0.68 \text{ mm}^2)$ and low percent obstruction of the stent area (10.97 \pm 7.96%). At 6-month follow-up, when the healing cascade is closer to a definitive result, NIH accumulation was greater (210 \pm 70 µm) as compared to what was seen at three months (p<0.001). Conversely, NIH area was 1.74 ± 0.73 mm² and resultant obstruction of the stent area was 24.56 \pm 9.09%. Further, 99.77% of struts per lesion were covered, suggesting that all stents were virtually entirely covered at six months. Of note, no incomplete stent apposition was observed.

Dr. Kaul said that "the results of the present study depict a well-balanced safety (high strut coverage) and efficacy (low NIH accumulation) profiles of Tetrilimus stents at 3-month and 6-month OCT follow-ups."



Sex Differences in Instantaneous Wave-free Ratio (iFR) or Fractional Flow Reserve (FFR) **Guided Strategy**

Instantaneous wave-free ratio (iFR)- and fractional flow reserve (FFR)-guided strategies have shown the artery disease. Two years ago, the result of DEFINEguided treatments as the DEFINE-FLAIR substudy.

In this study, 601 women and 1,891 men who were randomized to iFR- or FFR-guided strategy were analyzed. iFR \leq 0.89 and FFR \leq 0.80 were used as the criteria for revascularization. The primary endpoint was 1-year major adverse cardiac events (MACE), defined as the composite of all-cause death, nonfatal myocardial infarction, or

Chee Hae Kim. MD

eoul National University Hospital

unplanned revascularization.

This study found that there was no gender difference in iFR values (0.91 ± 0.09 vs. 0.91 ± 0.10, p=0.442), but FFR values were higher in women $(0.85 \pm 0.10 \text{ vs.} 0.83 \pm 0.09)$, p=0.001). In men, iFR-guided strategy was associated with a significantly lower rate of revascularization than FFRguided strategy (49.3% vs. 57.1%, p=0.012). However, in women, revascularization rate was not different between iFR- and FFR-guided group (41.4% vs. 42.6%, p=0.656). At 1 year, MACE rate was not different according to gender (5.49% vs. 6.77%, hazard ratio [HR] 0.80, 95% confidence interval [CI] 0.53 to 1.21, p=0.282). And there was no significant difference in MACE rates between iFR- and FFR-guided strategies in both women (5.36% vs. 5.61%,

HR 0.86, 95% CI 0.40 to 1.81, p=0.683) and men (6.55% vs. 7.00%, HR 0.97, 95% CI 0.67 to 1.41, p=0.888) (interaction p=0.76) (Figure 2).

"This DEFINE-FLAIR substudy shows that there is no difference in iFR values according to gender, but FFR values is higher in women," said Dr. Kim. She insisted that iFR- and FFR-guided treatment strategies have comparable clinical outcomes regardless of gender.

Late-Breaking Research Abstracts

- TCTAP 2019 Featured Clinical Research from Abstracts
- » Monday, April 29, 11:00 AM 11:45 AM
- » Presentation Theater 1. Level 1

B. Men



8 HR 0.86, 95% CI 0.40-1.81, p=0.683 HR 0.97, 95% CI 0.67-1.41, p=0.888 4 5 6 7 8 9 10 11 12 Inths since randomisation - iFR - FFR

Figure 2. Comparison of MACE between iFR and FFR-guided strategies according to sex



um Coronary Stent System



4 5 6 7 8 9 10

- FFR

833 807 796 788 784 765 633 841 813 799 792 785 765 622

- iFR





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Endovascular Symposium



Osamu lida. MD ansai Rosai Hospital.

ntraVascular ultrasOund suppoRted endovascular therapy in femoropopliteal arterY disease: 12-months results from the **IVORY-study**

Endovascular therapy (EVT) is the primary treatment of symptomatic femoropopliteal (FP) arterial disease attributed to the development of novel interventional techniques and anti-restenostic devices leading to distinctly improve in the short- and long-term outcomes. Consequently, the recommended applications of EVT have expanded through guidelines, being nowadays widespread use in clinical practice. However, the treatment outcomes after FP-EVT are still inconsistent, and the recommendations vary among guidelines. When performing vascular intervention, intravascular ultrasound (IVUS) plays an important role for accurately evaluating vessel diameters, characteristics and morphologies. IVUS is now also adopted in the field of FP-EVT and its improvement of clinical outcomes of FP-EVT is anticipated. The aim of the current prospective, multicenter IVORY study was to reveal the clinical outcomes of IVUS-supported EVT for FP lesions and its associated factors in real-world practice.

The IVORY Registry was a prospective, multicenter, observational study, registering adult patients in whom FP-EVT with assistance of IVUS was planned for symptomatic atherosclerotic PAD (Rutherford category 1 to 6), between November 2015 and June 2017. Registration was in advance of EVT, and patients in whom bypass surgery and/or major amputation after EVT was originally planned were excluded. The study subjects were enrolled in 33 participating centers all over Japan, and were followed-up to one year. The primary outcome measure of the study was primary patency one year after EVT. The study was in accordance with the Declaration of Helsinki, and was approved by the ethics committee of each participating center. Written informed consent was obtained from every participant or if impossible from his/ her family.

The proportion of 1-year primary patency was estimated at 64.4% (95% confidence interval 62.2 to 66.6%). Multivariate analysis demonstrated that 1-year primary patency was significantly associated with distal reference vessel diameter (adjusted odds ratio 1.42 [95%



Lawrence A. Garcia. MD St. Flizabeth's Medical Center. 1150

confidence interval 1.21 to 1.66] per 1-mm increase, i.e., 0.74 [0.63-0.88] per 1-mm decrease, p=0.001), lesion length (0.75 [0.64 to 0.87] per 10-cm increase, p<0.001), chronic total occlusion (0.70 [0.52-0.94], p=0.018), spot stenting (1.58 [1.01 to 2.46], p=0.043), full-covered stenting (2.67 [1.99 to 3.60], p<0.001), DES/SG use (1.94 [1.30 to 2.90], p=0.001), and statin administered throughout the follow-up period (1.58 [1.23 to 2.04], p<0.001) (Figure 1).

The current study demonstrated acceptable clinical outcomes of IVUS-supported FP-EVT for real-world population. Regarding predictors for 12-month restenosis, anatomical, procedural, and device-related factors were significantly associated with 12-month restenosis, whereas systemic and affected limb-related factors were not.

A therectomy for BTK Vessels: Current Status

As for the superficial femoral artery (SFA), below the knee (BTK) interventions has grown in both scope and scientific data. However, unlike the SFA, the data set has been mired from mostly registry outcomes. Apart from the unique location, BTK vessel intervention has for the most part been limited to but not exclusive for patients with critical limb ischemia (CLI) in many, if not, all well-performed trials. Most protocols have looked at BTK intervention from a metric of amputation free survival (AFS). This remains a low bar metric that has in the past been the benchmark for simple balloon angioplasty (POBA)

In the review of outcomes for any device in the BTK space and specifically for atherectomy in this location, AFS remains a principal outcome. The current status for atherectomy in the BTK space is principally driven to the fact that where calcification in the above knee SFA/popliteal segment can be daunting and in many cases recalcitrant; it appears to be the rule ion BTK and not the exception. Due in fact to the unique buildup of atherosclerosis in this region and the high preponderance of calcification, atherectomy appears to have a key niche here.

Over the years there have been several critical trials driven to the infra-popliteal space using atherectomy. First, OASIS (CSL xx, USA) evaluated the device in 3 cm lesions of the popliteal and infra-popliteal space in a core lab adjudicated manner. This trial demonstrated

LIBERTY trial, which

and presented with

12-month outcomes.

demonstrated that for

Rutherford-Becker (RB)

class 4-5 or RB class 6

subjects that against

a backdrop of major

adverse limb events

(MALE), use of orbital

atherectomy provided excellent outcomes.

Here, this registry,

principally driven

by users of CSI,

was recently completed

the safety of the device with a good profile of limited complications. However, the largest trial from CSI was the

Independent risk factors for 1-year restenosis

	Adjusted odds ratio for 1-year restenosis
FP lesion characteristics	
Distal reference vessel diameter (per 1-mm decrease)	1.34 [1.14-1.59] (P=0.001)
Lesion length (per 10-cm increase)	1.32 [1.12-1.55] (P=0.001)
Chronic total occlusion	1.39 [1.03-1.87] (P=0.029)
Endovascular procedures	
Full-covered stenting	0.42 [0.31-0.58] (P<0.001)
Drug-eluting stent or stent graft use	0.51 [0.34-0.77] (P=0.001)
Post-procedural characteristics	
Minimum lumen area (per 10-mm ² increase)	0.70 [0.54-0.92] (P=0.009)
Medication kept during FU	
Statin use	0.64 [0.49-0.82] (P=0.001)



Osami Kawarada. MD uwakai Memorial Hospital. lanan

Unfortunately, this trial did not report the primary patency in these patient groups but only the MALE. The other critical take away with this trial was that for the worst of the worst, patients of RB class 5 and importantly 6. Although one may achieve an adequate result at the index procedure, repeated interventions are the norm within 6 months and not the exception.

Other atherectomy devices, such as directional, were reported 5 years ago in the DEFINITIVE LE trial. In this trial, core lab adjudicated, had 200 subjects of 800 with CLI. The lesions treated with SilverHawk (Medtronic Inc. Minneapolis, MN, USA) were up to 20 cm long and in the infra-popliteal segment measured an average of 6 cm. The outcomes reported both the primary AFS at 95% but also reported the primary patency in the tibial circulation of 78% on this 6 cm metric using the PSVR of 2.5. In the claudicant cohort of those subjects treated with atherectomy in the BTK location, their primary patency using the same 2.5 PSVR was 90% on a similar 6.0 cm lesion length

An alternative to the above atherectomy devices currently is the lithoplasty system by Shockwave (shockwave inc., xx, USA). In the DISRUPT BTK study, treating lesion length of 52 mm and 100% with moderate to severe calcification, the primary goal was expansion of the artery alone with lithoplasty. This occurred in 47% of the subjects and 100% achieved dilation with adjunctive POBA. The safety profile in this cohort of only 19 patients was impressive. No distal emboli and only 1 dissection (4.8% 1/19) occurred.

Overall, atherectomy today remains appealing for calcified lesions and the data set, though sparse and nonrandomized, appear to support its use in the BTK vessels. The new comer to the party may be lithoplasty, which as in the above knee location may allow vessel compliance changes without the need for further atherectomy devices, thereby limiting embolization and costs on the index procedure.

Skin Perfusion Pressure-guided Intervention

The utility of ankle-brachial index (ABI) is limited in the management of critical limb ischemia (CLI) because of the underlying tibial calcification and the below the ankle lesions. According to the previous study regarding the relationship between ABI and probability of wound healing, in patients without diabetes mellitus or renal failure that are very common in CLI, a good relationship can be observed. However, in patients with diabetes mellitus or renal failure such kind of relationship is gone.

There is an increasing awareness of the importance of foot microcirculation such as skin perfusion pressure (SPP) in the management of CLI. According to the previous study, there is a significant relationship between foot SPP and probability of wound healing. If foot SPP of 40 mmHg can be achieved, the probability of wound healing is over 90%. That is why the cut off point of foot SPP for the diagnosis of CLI is considered to be 40 mmHg, and the endpoint of intervention should be foot SPP 40 mmHg. The following is a comprehensive treatment strategy for suspected or definite CLI patients under the SPP guidance (Figure 2). 1) If the patient's foot SPP is higher than 40-50 mmHg, the priority is wound care or debridement. 2) If the patient's foot SPP is below







Figure 1. Independent risk factors for 1-year restenosis

Figure 4. Endovascular strategy for below-the-ankle lesions

40-50 mmHg and the wound is not complicated by severe bacterial infection, revascularization should be followed by debridement. 3) If the patient's foot SPP is below 40-50 mmHg and the wound is complicated by severe bacterial infection, the priority is debridement before revascularization.

The following is endovascular strategy for multisegment disease or isolated infrapopliteal disease in CLI (Figure 3). Especially in cases of multi-segment disease, upstream revascularization needs to be undertaken because aortoiliac intervention is durable and femoropopliteal intervention is developing. And then, if the patient's foot SPP is below 40-50 mmHg even after the upstream revascularization or in cases of isolated infrapopliteal artery disease, at least one straight-line based on angiographic findings in the field of infrapopliteal artery disease should be established. If the patient's foot SPP still remains below 40 mmHg even after the first infrapopliteal intervention, further intervention including another tibia/ peroneal intervention or below the ankle intervention should be considered.

The following is endovascular strategy for symptomatic below-the-ankle

lesions (Figure 4). Indication of belowthe-ankle intervention also needs to be considered based on the SPP guidance. In cases where the below-the-ankle lesions are separate from the above-theankle lesions (separate type), below-theankle intervention is not recommended during the first intervention because complications related to endovascular procedure and post-intervention reocclusion can potentially be catastrophic. For cases of extensive serial lesions beyond the ankle joint (serial type) or isolated below-the-ankle lesions (isolated type), treating below-theankle lesions is recommended in the first intervention

Endovascular Symposium

» Tuesday, April 30, 2:00 PM - 6:00 PM » Structural Heart & Endovascular Theater. Level 1



8-9 **24th cardiovascular summit TCTAP2019 Daily News**

Structural Heart Disease



loke V. Finn. MD

Durability of TAVR versus SAVR: Pathologic Insights

Transcatheter aortic valve replacement (TAVR) is quickly becoming the standard of care when treating patients with aortic stenosis (AS). Recent results from PARTNER 3 and CoreValve trials in patients at low surgical risk show non-inferior or superior results to surgical aortic valve replacement (SAVR) at one year. However, the durability of TAVR valves remains an important unresolved question. Generally, SAVR (bioprosthetic valves) have limited durability beyond 10 years, especially in younger patients with valves undergoing degeneration or tears, calcification, pannus formation and endocarditis at a rate of approximately 1% per year (excluding first year where events of endocarditis is higher). Clinical studies so far suggest durability may be similar between TAVR and SAVR with a very low percentage of structural valve deterioration out to 5 years (Bourguignon T, et al. Ann Thorac Surg 2016;99(3):831-837, Didier R, Circulation 2018;138:2597-2607).

Very few pathologic studies of long-term TAVR integrity have been reported. We conducted a study of 86 TAVR valves (64% Medtronic/22% Edwards) removed at autopsy or surgery of greater than or equal to 30 days of implant duration (median 252 days). Valves were assessed by duration of implant into 3 groups; ≥30-180 days, >180 days-2 years, or >2 years. No calcification was observed between ≥30-180 days, however, calcification score increased mildly from >180 days-2 years to >2 years. The implant duration of cases with leaflet calcification was longer than those without calcification (p=0.0002). Thrombus score was low overall and peaked at >180 days-2 years and declined thereafter. Structural changes were minimal to mild and increase with duration of implant.

These data are consistent with mean gradient data reported for both the PARTNER and CoreValve trials over 5 years. Overall structural changes of the leaflet are the main cause of late SAVR failure. This analysis shows acceptable durability in TAVR valves by pathological

analysis done comparing TAVR valves of different durations but is limited by the small sample size of longterm implants (>2 years=23 valves). Further analysis needs to be performed to understand whether the durability of TAVR is similar or better than that for SAVR before TAVR can become the standard of care for young low surgical risk patients.

Morning Roundtable Forum: Meet the Experts over Breakfast Valves

» Monday, April 29, 7:00 AM - 8:10 AM » Presentation Theater 2, Level 1



Yesterday's Hot Lives

A 63 year-old female was admitted for effort chest pain. Her coronary risk factor was hypertension. She underwent percutaneous coronary intervention (PCI) at left main (LM) to proximal left anterior descending (LAD) artery 2 years ago. Coronary angiogram showed severe stenosis at proximal left circumflex (LCX) ostium, patent stent from LM to proximal LAD, and moderate stenosis at mid LAD. The fractional flow reserve (FFR) value of mid LAD was 0.81. We planned to use the Culotte technique.



coronary (LCX) artery territory. The coronary



Left coronary artery was engaged with a 8 Fr XB 3.5 guiding catheter. Using the BMW guidewire, we passed LAD then the Sion guidewire was inserted into LCX. We used NC Trek balloon 2.75 x 20 mm for plague modification at LCX and Xience Sierra stent 3.5 x 28 mm was implanted from proximal LCX to distal LM to minimally overlap the previous LM stent. Then, the guide wires were crossed and reinserted on the opposite side (i.e., LAD guide wire to LCX and vice versa). IKAZUCHI Zero 1.5 x 15 mm balloon,

Emerge NC 3.5 x 15 mm balloon and Sapphire NC 3.75 x 15 mm balloon were used to widen LAD stent sequentially. Finally, Kissing balloon was applied at proximal LAD with Sapphire NC 3.75 x 15 mm balloon and proximal LCX with Sapphire NC 3.5 x 15 mm balloon. The final angiography showed a wellpositioned and expanded stent with TIMI 3 flow.

A 66 year-old female was admitted for dyspnea on exertion 2 months ago. Her coronary risk factors were hypertension and hyperlipidemia. She underwent percutaneous coronary intervention (PCI) at proximal to mid left anterior descending (LAD) artery and proximal to mid right coronary artery (RCA) an year ago, and had dyspnea 2 months ago. Thallium single photon emission computed tomography (SPECT) revealed a large perfusion defect in the left circumflex angiography was performed, which revealed severe stenosis at proximal LCX and obtuse marginal (OM)

branch. Her SYNTAX score was 13 points.

Left coronary artery was engaged with a 8 Fr JL4 guiding catheter. Two BMW guidewires were inserted to LAD and LCX. We checked LAD and LCX using intravascular ultrasound (IVUS). He used an Emerge NC 2.5 x15 mm at OM branch and a Xience Sierra 2.5 x 15 mm was implanted at OM branch. Then, we treated proximal LCX ostium lesion using the Culotte technique. He used a Raiden 3.5 x 15 mm NC balloon at proximal LCX. After balloon, Xience Sierra 3.5 x 23 mm was implanted at left main to proximal LCX. BMW wire was reinserted to LAD and a Sapphire NC

2.5 x 15 mm was applied at left main to proximal LAD. Sequential post-dilations were performed using a Powered Lacrosse 3.5 x 15 mm for left main to proximal LCX and Sapphire NC 4.0 x 15 mm for left main to proximal LAD. Kissing balloon was applied at proximal LAD with Sapphire NC 4.0 x 15 mm and Powered Lacrosse 3.5 x 15 mm at proximal LCX. The final angiogram and IVUS showed a well-positioned and expanded stent with good distal run-off flow.





10-11 24th cardiovascular summit TCTAP 2019 Daily News

Master the CTO



Kenva Nasu. MD ovohashi Heart Center

VUS-guided Entry in Stumpless Proximal **Cap and Thereafter**

Where is the best puncture point? Stumpless CTO with side branch is one of the most challenging lesion subsets in CTO-PCI. Commonly, the puncture wire can reach the carina side of the occluded segment at the distal end of the bifurcation (Figure 1A). Mechanically, the puncture wire can be deflected after hitting carina. However, it can also go into the sub-intimal space from the most proximal site of CTO segment. To get into the true lumen, the operator should try to insert the puncture wire toward the plague at the most proximal side of bifurcation if possible. Case1 shows stumpless CTO at the bifurcation of the distal RCA with graft failure (Figure 1B). After failure to puncture the stump with GAIA NEXT 2 and 3, Conquest 12 g with CARAVEL (ASAHI INTECC) could penetrate the plaque at the proximal side of the bifurcation (Figure 1C). After advancement of the conquest 12g wire on the angiogram, the puncture wire



Osuna Kwon, MD The Catholic University of Korea, Funpyeong St. Marv's Hospital. Korea

position at bifurcation was confirmed by the IVUS (Figure **1D**). The deviated portion of the guidewire is located at the proximal side of the bifurcation.

Pieces of equipment for IVUS guided penetration Eagle Eve (Volcano) and Opticross (Boston Scientific) are commercially available worldwide. Opticross can be used in 7 Fr guiding catheter with some microcatheters such as Finecross (TERUMO) or CARAVEL. The Finecross and CARAVEL microcatheter can be used in 7 Fr guiding catheter with the IVUS. On the other hand, if dual lumen catheter such as Crusade (Kaneka) or SASUKE (ASAHI INTECC) is needed to get stronger back-up force for the puncture, 8 Fr guiding system is needed to put two wires, IVUS catheter, and dual lumen catheter together.

After Penetration of the proximal cap Following penetration with hard guidewire such as Miracle, GAIA, or Conquest family, microcatheter should be inserted into the CTO body. After that, downgrading to a softer tip wire is strongly recommended. Case 2 shows a mid-RCA CTO with



Figure 1. Case 1: Puncture site of prox



Figure 2. Case 2: Step down technique after penetration



Figure 3. Case 3: Non tapared wire for reverse CART

ambiguous proximal cap (Figure 2A).

After penetrating the cap with an Ultimate Bros 3 with the IVUS guidance (Figure 2B), the guidewire was changed to XT-R. XT-R could get into a small RV branch (Figure 2C) but ultimately went into the distal true lumen (Figure 2D).

In the retrograde approach, changing the guidewire to a non-tapered 0.014 inch tip is better to deliver the balloon smoothly for the reverse CART. Case 3 shows a second attempt to mid-LAD CTO with abrupt proximal cap (Figure **3A)**. After tracking the retrograde channel, IVUS guided antegrade puncture has been performed with a GAIA NEXT 2 (Figure 3B). The guidewire was changed to the Ultimate bros 3 to complete the reverse CART (Figure 3C and D).

VUS-guided Stent Optimization: How Large from AMC Data

Clinical significance of post-stent intravascular ultrasound for chronic total occlusion percutaneous coronary intervention with drug-eluting stents

Recently, randomized trials and meta-analyses have clearly demonstrated that implantation of intravascular ultrasound (IVUS)-guided drug-eluting stents (DES) significantly improved clinical outcomes, primarily driven by a decreased risk of target lesion revascularization (TLR), compared with angiography-guidance. IVUS is a useful tool for planning percutaneous coronary intervention (PCI) by informing the operators of lesion severity, reference vessel size, lesion length, and extent of calcification. With validated criteria for stent underexpansion and edge problems, post-stent IVUS has been used to optimize stent deployment to prevent stent failure (restenosis and early thrombosis).

However, few studies have evaluated its use for chronic total occlusion (CTO) intervention and data is lacking regarding the definite role and cutoff value for optimal stent expansion in CTO intervention using DES. Thus, this study aimed (1) to evaluate benefits of performing post-stent IVUS for preventing stent failure (TLR), (2) to identify IVUS parameters for predicting TLR, and (3) to assess the cutoff values of the IVUS parameters.

From January 2007 to December 2016, a total of 1,077 successful cases of CTO-PCI with DES were included for the present study. Among them, post-stent IVUS was performed in 838 (77.8%) while remaining 239 (22.9%) cases did not undergo post-stent IVUS. For IVUS analysis, a total of 115 cases were excluded because of the absence of post-procedure IVUS imaging, poor image quality, and incomplete imaging of the entire stent. Finally, 723 lesions were included in the analysis. Clinical outcomes during the median follow-up period of 6.3 years (interquartile range [IQR]: 3.5 to 9.0 months) was assessed.

Patients undergoing post-stent IVUS had a higher prevalence of prior coronary artery bypass grafting, left anterior descending disease and in-stent restenosis (ISR), and received second generation DES more frequently, as well as stents with slightly larger diameter. After adjustment with the use of inverse probability weighting, all covariates were well-balanced.

In the unweighted population, patients who underwent post-stent IVUS had a significantly lower cumulative TLR/ reocclusion rate (9.7% vs. 16.8%, hazard ratio [HR], 0.58; 95% confidence interval [CI], 0.36 to 0.93, p=0.02) compared to those without post-stent IVUS (Figure 4A). This difference largely contributed to the lower incidence

of target lesion failure TVR/reocclusion (21.5% vs. 34.7%,

HR, 0.60; 95% CI, 0.44 to 0.81, p=0.001) in the post-stent IVUS group. These results were consistent in the weighted population. Patients undergoing post-stent IVUS had a significantly lower risk of TLR/reocclusion (HR, 0.54; 95% CI, 0.34 to 0.86, p=0.01) compared to those without poststent IVUS. (Figure 4B) The risk of target-lesion failure was significantly lower in the post-stent IVUS group. There were no significant differences between two groups with respect to the risks of death and target-vessel myocardial infarction (MI) and stent thrombosis.

Using multivariable logistic regression analysis, the only independent predictor of TLR was absolute minimal stent area (MSA) (HR, 0.78; 95% CI 0.64 to 0.95; p=0.01). Sensitivity and specificity curves were used to identify the







CASE SUBMISSION JANUARY 14-MAY 3, 2019

Invitation as a Faculty Member of 2020 Advantages for TCTAP Best Young Scientist Award AUC = 0.632

95% CI 0.60 - 0.67

P value = 0.001

Sensitivity: 63.0%

Specificity: 58.3%

optimal cutoff values of minimum lumen area (MLA) that best predicted TLR after CTO-PCI with DES implantation: 4.9 mm2 for MLA. The sensitivity and specificity for MLA <4.9 mm2 were 63.0% and 58.3%, respectively, with area under curve (AUC) of 0.632 (p=0.001) (Figure 5).

In 273 follow-up coronary angiography cases in the poststent IVUS group, of 273 proximal reference segments, 22 (8.1%) showed proximal edge restenosis. For the prediction of proximal edge restenosis, the cutoff for the reference plaque burden was 58.9% with a sensitivity of 70.0% and specificity of 74.1%. Of 273 distal reference segments, 28 (10.3%) showed distal edge restenosis. For the prediction of distal edge restenosis, the cutoff for the reference plaque burden was 46.5% with a sensitivity of 79.2% and

specificity of 55.0%.

The present study demonstrated that in CTO-PCI with DES, subjects with post-stent IVUS evaluation were associated with a reduction of TLR compared to those without poststent IVUS. In addition, MSA was identified as a strong, independent predictor of TLR and the cutoff value of MSA was 4.9 mm²

Master the CTO

- » Tuesday, April 30, 8:30 AM 6:00 PM
- » CTO Theater, Level 1



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Stent MSA (mm²)

es of final MSA that predicted target lesion revascularization

Figure 5. The sensitivity and specificity curve identified optimal cutoff

2 3 4 5 6 7 8 9 10 11 12

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Yesterday's Highlights

Glorious Best Presenters from Competition Session

A number of interesting abstracts were submitted from all over the world to TCTAP 2019, and then a few abstracts, and cases were selected to be presented at the Moderated Competition after being strictly reviewed by the scientific committee.

Approximately 125 authors made presentation at the Moderated Abstract, and Case Competition Session and only 23 presenters were selected as the Best Presenters after evaluation.

Best Abstract Presenters

- 1-7. Complex PCI: **Shu-I Lin** (Taiwan)
- 1-8. Imaging & Physiology: Kunihiro Shimamura (Japan)
 1-9. Acute Coronary Syndromes: El Sayed Farag (Egypt)
 1-10. Imaging & Physiology: Kosei Terada (Japan)
 2-7. Coronary Intervention: Hiteshi KC Chauhan (India)
 2-8. Structural Heart Disease: Rie Nakayama (Japan)
 2-9. Endovascular Intervention: Seung-Woon Rha (Korea)
 2-10. Endovascular Intervention: Indulis Kumsars (Latvia)

Best Case Presenters

1-7. Endovascular Intervention: Wiwat Kanjanarutjawiwat (Thailand)
1-8. Endovascular Intervention: Dainis Krievins (Latvia)
1-9. Endovascular Intervention: Shawal Faizal Mohamad (Malaysia)
1-10. Complex PCI: Hong Nyun Kim (Korea)
1-11. Complex PCI: Swapnil Dhondibhau Mate (Taiwan)
2-7. Structural Heart Disease: Cheng-Yu Ko (Taiwan)
2-8. Structural Heart Disease: Cheng-Yu Ko (Taiwan)
2-9. Structural Heart Disease: I-Fan Liu (Taiwan)
2-10. Complex PCI: Sarat Kumar Sahoo (India)
2-11. Complex PCI: Chi-Yao Huang (Taiwan)
3-6. Complex PCI: Dong-Yi Chen (Taiwan)
3-7. Endovascular Intervention: Cheng-Hsuan Tsai (Taiwan)
3-8. Endovascular Intervention: Patrick Yan-Tyng Liu (Taiwan)
3-10. Endovascular Intervention: Chi-Yen Wang (Taiwan)





PAGE | **24th** CARDIOVASCULAR SUMMIT 14-15 TCTAP2019 Daily News

Hot Abstracts & Case



Youna Hoon Seo. MD Konvang University Hospital. Korea

ong-term Clinical Outcomes in Patients with Untreated Non-culprit Intermediate Coronary Lesion and Evaluation of Predictors by Using Virtual Histology-Intravascular Ultrasound; A Prospective Cohort Study

It is uncertain whether the coronary lesion with intermediate stenosis is more likely to cause cardiovascular events than a normal or minimal lesion. Dr. Young Hoon Seo of Konyang University Hospital, Korea, presented the clinical outcomes of the single-center, prospective cohort study, which was conducted to identify long-term clinical outcomes of patients with the untreated non-culprit intermediate lesion and evaluate its cardiovascular predictor by using virtual histology-intravascular ultrasound (VH-IVUS). Subjects with non-culprit intermediate lesion underwent VH-IVUS (Figure 1) were enrolled after percutaneous coronary intervention at the culprit lesion. Intermediate lesion was defined as 30% to 70% stenosis in coronary angiography and primary outcome was an occurrence of major adverse cardiovascular events (MACE) defined as all-cause death, target lesion revascularization (TLR), non-TLR (unplanned revascularization elsewhere in the target vessel or in other coronary arteries which looked normal or minimal stenosis), cerebrovascular events or non-fatal myocardial infarction (MI). The mean follow-up period was 4.2 years. The presented figure represents angiographic and VH-IVUS images of patients whose intermediate lesion progressed rapidly and underwent revascularization after 9 months. Total 25 MACE were identified in 86 patients with 89



sef Veselka MD ech Republic

intermediate lesions. Diameter stenosis (OR 1.07, p=0.015), plaque burden (PB, OR 1.07, p=0.040), fibro-fatty area (FFA, OR 1.61, p=0.016), PB ≥70 % (OR 3.93, p=0.018) and area stenosis ≥50% (OR 2.94, p=0.042) showed significant relationships with an occurrence of MACE. In multivariable Cox-proportional hazard analysis, FFA in intermediate lesion was significantly associated with MACE.

Dr. Seo concluded, "Untreated intermediate lesions had a significantly higher chance for requiring revascularization compared with a normal or minimal lesion. And also, a large FFA in intermediate lesion was a significant predictor of cardiovascular events and which finding was mainly driven by coronary-related events, in particularly intermediate lesion progression".

Moderated Abstract Competition I 1-8. Imaging & Physiology » Monday, April 29, 10:10 AM - 10:20 AM » Abstract Zone I, Level 1

Short- and Long-term Outcome of Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy in Patients with Mild Left Ventricular Hypertrophy: A Propensity Score Matching Analysis

Based on European guidelines, alcohol septal ablation (ASA) for hypertrophic obstructive cardiomyopathy (HOCM) is



Figure 1. A: Baseline, B: After 9 months

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Yuii Nishimoto. MD Hyodo Prefectural Amadasaki General Medical Center, Japan

indicated only in patients with interventricular septum (IVS) thickness > 16 mm. In this regard, Dr. Josef Veselka from Charles University Hospital, Prag, Czech Republic presented the results of the study, which aimed to evaluate the effect of ASA in patients with mild hypertrophy (IVS \leq 16 mm).

A total of 1,505 patients with symptomatic obstructive HCM (HOCM) underwent ASA between 1997 and 2017 and were enrolled in this study. Procedures were performed in tertiary HCM centers with a number of performed ASA >50 at each site. Propensity score was used to match 172 pairs (344 patients) in groups IVS \leq 16 mm or IVS >16 mm. There was no occurrence of a post-ASA ventricular septal defect in the whole cohort (n=1,505). Matched patients had 30-day mortality rate 0% in IVS \leq 16 mm group and 0.6% in IVS >16 mm group (p=1). Patients in IVS \leq 16 mm group had more ASA-attributable early complications (16% vs 9%; p=0.049), which was driven by the higher need for pacemaker implantation (13% vs 8%; p=0.22). The mean follow-up was 5.4 ± 4.3 years and the annual all-cause mortality rate was 1.8 and 3.2 deaths per 100-patient-years in IVS \leq 16 group and IVS >16 group, respectively (log-rank test p=0.04). There were no differences in symptom relief and left ventricular (LV) gradient reduction. Patients with IVS \leq 16 mm had less repeated septal reduction procedures (log-rank test p=0.03).

Dr. Josef Veselka concluded, "Selected patients with HOCM and mild hypertrophy (IVS ≤16 mm) had earlier post-ASA complications driven by the need for pacemaker implantation, but their long-term survival is better than in patients with IVS >16 mm. While relief of symptoms and LV obstruction reduction is similar in both groups, a need for repeat septal reduction is higher in patients with IVS >16 mm"

Moderated Abstract Competition II

- 2-8. Structural Heart Disease » Monday, April 29, 10:30 AM - 10:40 AM
- » Abstract Zone II, Level 1

A Novel Technique: Pathing Through Bulky **Calcified Nodules Projecting into a Popliteal** Artery by Using TruePath[™] Crossing Device

Yesterday, Dr. Yuji Nishimoto of Hyogo Prefectural Amagasaki General Medical Center, Japan, presented a case of "CanPath technique" for severely calcified popliteal lesion. An 84-year-old man on dialysis presented to the hospital with ischemic pain at rest of his left toes

(Rutherford classification 4). His popliteal, posterior tibial, and dorsalis pedis pulses were not palpated. His medical history was coronary artery disease after a coronary artery bypass graft surgery and cerebral infarction. His left ankle-brachial index (ABI) was 0.48. Pre-procedural angiography revealed an eccentric severe stenosis with bulky calcified nodules projecting into the left popliteal artery (Figure 2). After crossing the lesion with a tapered tip 1 g guidewire, and dilatation with a 1.5 mm balloon, intravascular ultrasound (IVUS) demonstrated eccentric bulky calcified nodules. A conventional bigger balloon dilatation in this lumen would cause an under-expansion, therefore we tried a novel CanPath technique: pathing through bulky Calcified nodules by using a TruePath (Boston Scientific, Natick, Massachusetts), which could create an intraluminal pathway using a rotating distal diamond-coated tip. The calcified nodules were penetrated by using the TruePath and dilated with a 1.5 mm balloon. The IVUS showed the wire in the middle of the calcification. After dilatation with a 4.0 mm cutting



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balloon, the IVUS showed some cracks in the calcification. Finally, they dilated with a 5.0 mm balloon for a long time. A final angiogram and IVUS demonstrated the lesion had become well-expanded without a stent implantation. However, endovascular treatment of the popliteal artery, which is a non-stenting zone, with severely calcified lesions remains challenging in terms of a lesion modification and the long-term patency. The CanPath technique could be useful for providing a sufficient lumen area.

Dr. Yuji Nishimoto commented, "Endovascular treatment of the popliteal artery, which is a non-stenting zone, with severely calcified lesions remains challenging in terms of a lesion modification and the long-term patency. The CanPath technique could be useful for providing a sufficient lumen area".

Moderated Complex Case Competition I 1-9. Endovascular Intervention » Monday, April 29, 11:40 AM - 11:50 AM » Case Zone I, Level 1

> Fiaure 2. procedural angiography



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