VLF
VASCULAR LEADERS FORUM
Presented by VIVA

DRUG ELUTION IN PERIPHERAL ARTERY DISEASE:

A CRITICAL ANALYSIS FROM A MULTISPECIALTY CONSORTIUM

March 1-2, 2019
Washington DC
Kimpton Palomar Hotel
Phillips Ballroom

VIVA

A NOT-FOR-PROFIT ORGANIZATION DEDICATED
TO VASCULAR EDUCATION AND RESEARCH
WWW.VIVAPHYSICIANS.ORG/VLF

Welcome to this special session of the Vascular Leaders Forum.

Late last year, a meta-analysis was published that suggested an association between drug-eluting device use in the context of treating PAD and increased mortality at 2 and 5 years. The results of the meta-analysis have given significant pause to many clinicians. Since the publication, trials using drug-eluting technologies have been halted in Europe while the FDA issued a statement asking for "continued surveillance" while they investigate. We believe this provides an opportunity for the vascular community to rise to the occasion, put our patients first, and organize the entire set of data in this area to provide the clearest understanding of the current state of paclitaxel-coated devices.

It's against the backdrop of these issues that VIVA Physicians, a not-for-profit organization with a mission to educate about, advocate for, and investigate vascular diseases, has brought together leading clinicians from around the world; regulatory bodies, societies, industry representatives; and, experts in clinical trial design and statistics to host a balanced, transparent, and comprehensive scientific discussion. To ensure a balanced review of the literature and the current meta-analysis, we've implemented a process to manage conflicts of interest and have posted each member of the Forum's commercial relationships on the following pages.

The ultimate goal of this program is to provide a foundational history of drug-based vascular devices and a glimpse into the current state of clinical affairs with an eye on the next steps needed to confirm the effects of paclitaxel in devices used to treat peripheral disease.

We have specifically designed the agenda with significant time for discussion forums in order to give each participant a voice in this important discussion and hope that you participate robustly in this special Vascular Leaders Forum. Ultimately, we plan to publish these proceedings.

Best,

2019 Vascular Leaders Forum Steering Committee

Gary Ansel, MD
Joshua Beckman, MD
Michael R. Jaff, DO
John Laird Jr, MD
Kenneth Rosenfield, MD
Peter Schneider, MD
Christopher White, MD

AUDIENCE RESPONSE SESSION

We will be using an Audience Response System during VLF. All answers will be displayed during the presentation. This session is designed to gather feedback from practicing physicians. Unless otherwise noted, this session is not designed for industry or participants who are not practicing clinicians.

BADGES

Please wear your VLF badge to all functions.

MEALS

Lunch will be served at Urbana Restaurant (1st floor of the hotel).
Breakfast, breaks and the reception will be in the Freer room, adjacent to the Phillips Ballroom.

Friday, March 1

Breakfast	6:30 - 7:45 am
Break	10:25 - 10:50 am
Lunch	12:00 - 1:00 pm
Break	2:40 - 2:54 pm
Reception	5:00 - 6:00 pm

Saturday, March 2

Breakfast	6:30 - 7:45 am
Break	9:31 - 9:45 am

COMPLIMENTARY INTERNET ACCESS

Network: **Kimpton Meeting**
Password: **VLF2019** (case sensitive)

VIDEO RECORDING & LIVE STREAMING

The Vascular Leaders Forum proceedings will be live streamed for those who are unable to attend the scientific session. With the amount of concern around such an impactful issue, VIVA will deliver these presentations and discussions globally and expeditiously to ensure clinicians have a more detailed context around the issues raised in the meta-analysis.

Video recordings of the entire meeting will also be available immediately following the event. Both the live stream and the archived recordings can be found at www.vivaphysicians.org/VLF.

DISCLOSURES

VIVA Physicians is committed to a transparent and balanced proceeding and believes that disclosure of potential conflicts of interest by participants is essential to the integrity of the process. Disclosures will also be displayed before each presentation. The following attendees have reported real or apparent conflicts of interest. These conflicts have been resolved through a peer-review process.

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No Reported Conflicts

Friday, March 1, 2019

6:30 – 7:45 am **Breakfast**

SESSION 1: BACKGROUND OF PAD AND MORTALITY

Moderators: Michael R. Jaff, DO, and Christopher White, MD
Panel: Nelson Bernardo, MD; Marianne Brodmann, MD; and Richard Neville, MD

8:00 – 8:10 am The Goal of This VLF: Introduction of Questions
Gary Ansel, MD

8:10 – 8:18 am Natural History of Intermittent Claudication: Real World vs Clinical Trial Population
Jeffrey Olin, DO

8:18 – 8:26 am Revascularization Outcomes Prior to the Advent of Drug-Based Technology: Surgery to Bare Metal Stents
Peter Schneider, MD

8:26 – 8:34 am What Are the Mortality Rates in the Published Randomized Vascular Device Trials?
Raghu Kolluri, MD

8:34 – 8:42 am Variables That May Affect Mortality in Patients With PAD
Joshua Beckman, MD

8:42 – 9:15 am **Panel Discussion**

SESSION 2: THE BASICS OF PACLITAXEL THERAPY AND PREVIOUS USE IN CORONARY VASCULATURE

Moderators: Joshua Beckman, MD, and D. Christopher Metzger, MD
Panel: Sanjay Misra, MD; Eric Secemsky, MD; and Giovanni Torsello, MD

9:15 – 9:23 am Unintended Consequences of Various Trial Designs and Their Potential Effect on Mortality and Other Outcomes
Ramon Varcoe, MBBS, MS, PhD

9:23 – 9:31 am Paclitaxel: Basic Pharmacology, Mechanism of Action, and Toxicity
Alfred Vargas, MD

9:31 – 9:39 am Use of Paclitaxel As a Primary Therapy in Oncology: Outcomes, Benefits, Adverse Events and Doses Compared to Devices
Erica Mayer, MD, MPH

9:39 – 9:47 am Evolution of Paclitaxel-Eluting Devices in Coronary Arteries
Ron Waksman, MD

9:47 – 9:55 am Why Has Paclitaxel Receded From Coronary Intervention?
Sahil Parikh, MD

AGENDA

Friday, March 1, 2019

9:55 – 10:25 am **Panel Discussion**

10:25 – 10:50 am **Break**

SESSION 3: THE BASIS OF PACLITAXEL USE FOR PAD

Moderators: Tony Das, MD, and Christopher White, MD
Panel: Barry Katzen, MD; Jonathan Michaels, MD; and Darren Schneider, MD

10:50 – 10:58 am Paclitaxel: Why Was This Chosen As a Vascular Antiproliferative Agent?
Lindsay Machan, MD

10:58 – 11:06 am Toxicity of Paclitaxel in Vascular Intervention:
What We Have Learned From Animal Studies
Aloke Finn, MD

11:06 – 11:14 am Drug-Delivery Kinetics: From Balloon to Stent
Elazer Edelman, MD, PhD

11:14 am – 12:00 pm **Panel Discussion**

12:00 – 1:00 pm **Lunch**

SESSION 4: BASIC META-ANALYSIS ANALYSIS AND THE JAHA META-ANALYSIS

Moderators: Michael R. Jaff, DO, and Christopher White, MD
Panel: Koen Deloose, MD; Lawrence Garcia, MD; and Joseph Mills, MD

1:00 – 1:15 pm Meta-Analyses: Statistical Benefits and Shortcomings
Sue Duval, PhD

1:15 – 1:30 pm The JAHA Meta-Analysis: The Why, the How and the Results
Konstantinos Katsanos, MD, PhD

1:30 – 1:45 pm A Critical Appraisal of JAHA Analysis
William Gray, MD

1:45 – 2:40 pm **Panel Discussion**

2:40 – 2:54 pm **Break**

Friday, March 1, 2019

SESSION 5: DRUG-ELUTING DEVICES AND CEC-ADJUDICATED TRIAL DATA
Moderators: Joshua Beckman, MD, and John Laird, Jr, MD
Panel: Joseph Chin, MD; Matthew Menard, MD; and Bret Wiechmann, MD

2:54 – 3:02 pm	The Clinical Advantages of Drug-Eluting Technologies for the Treatment of Patients With PAD *Patrick Geraghty, MD*
3:02 – 3:10 pm	From Sheath to Excrete: The Life-Cycle of Paclitaxel and What Is the Dose Response in the Vascular Patient *Aloke Finn, MD*
3:10 – 3:18 pm	Lessons From the Beginning: The THUNDER Trial and Long-term Follow-up *Thomas Zeller, MD, PhD*
3:18 – 3:54 pm	Mortality Outcomes, CEC, and our Internal Evaluation: DES: Zilver PTX—*Michael Dake, MD* Imperial—*William Gray, MD* Ranger II SFA – *Ravish Sachar, MD* DCB: Lutonix—*Kenneth Rosenfield, MD* IN.PACT—*John Laird, Jr, MD* Stellarex—*Sean Lyden, MD*
3:54 – 3:59 pm	Is There a Gender Difference in Efficacy and Mortality Outcomes? *Maureen Kohi, MD*
3:59 – 4:07 pm	DCB / DES in Critical Limb Ischemia Patients: Is the Risk Profile the Same? *Eric Secemsky, MD*
4:07 – 4:15 pm	What We Need to Look at: DCB Usage in AV Fistulae *Robert Lookstein, MD*
4:05 – 5:00 pm	**Panel Discussion**
5:00 pm	**Adjourn**
5:00 – 6:00 pm	**Reception**

AGENDA

Saturday, March 2, 2019

6:30 – 7:45 am **Breakfast**

SESSION 6: REGULATORY AROUND THE WORLD

Moderators: Joshua Beckman, MD, and Peter Schneider, MD
Panel: Brian DeRubertis, MD; Niten Singh, MD; and Ido Weinberg, MD

8:00 – 8:18 am The FDA Interpretation of the Meta-Analysis and What are We Looking for With the Data We Requested
Misti Malone, PhD

8:18 – 8:34 am A Clinical Trial Paradox: Reaction by EU and American Investigators to This Analysis
Mårten Falkenberg, MD, PhD, & Matthew Menard, MD

8:34 – 8:42 am How is the Meta-Analysis Being Dealt With in Japan?
Yoshiaki Yokoi, MD

8:42 – 8:50 am How Is the Meta-Analysis Being Dealt With in Europe?
Marianne Brodmann, MD

8:50 – 8:58 am Potential Legal Ramifications of This Meta-Analysis
Paul Rudolf, MD

8:58 – 9:31 am **Panel Discussion**

9:31 – 9:45 am **Break**

SESSION 7: HOW TO OPTIMIZE THE FUTURE

Moderators: Michael R. Jaff, DO, and Christopher White, MD
Panel: Tony Das, MD, and Alex Powell, MD

9:45 – 9:53 am Public Hysteria and Potential Adverse Impact on Patients: Is there a Better Way to Release Data?
Michael R. Jaff, DO

9:53 – 10:08 am The Power of Combining Patient Level Data
Krishna Rocha-Singh, MD

10:08 – 10:16 am Mining Existing Large Databases to Fill in Additional Knowledge Gaps
Marc Schermerhorn, MD

10:16 – 10:24 am Should We Change Our Trial Designs With Drug Based Technology in PAD Trials?
Stefan Müller-Hülsbeck, MD

10:24 – 10:32 am	Is There Any Role for *-limus* Drug-Coated Devices and Any Pertinent Timetables? *Peter Gaines, MD*
10:32 – 10:57 am	Relevant Publications Since the Meta-Analysis *Peter Schneider, MD; and Eric Secemsky, MD*
10:57 – 11:27 am	**Panel Discussion**
11:27 – 11:42 am	Where Do We Go From Here? *Gary Ansel, MD*
11:42 – 12:07 pm	Audience Response Session Final Discussion
12:07 – 12:15 pm	Closing Comments
12:15 pm	**Adjourn**

AFTER THE MEETING

VIVA will place transparency and collegiality at the forefront of our approach to the data and opinions presented to ensure any conclusions are developed from consensus.

The video recording will serve as both an extension and record of the VLF discussions. The Steering Committee will use these scientific presentations, information from the panel discussions, and consensus from the final audience response session as the framework for a follow up position paper that we hope to publish in the near future.

Publication:

VLF Publication Steering Committee

- Gary Ansel, MD
- Joshua Beckman, MD
- Michael R. Jaff, DO
- John Laird Jr, MD
- Peter Schneider, MD
- Christopher White, MD

Statistical Analysis:

Oversight Committee for Statistical Analysis of DCB/DES Data

- Krishna Rocha-Singh, MD (VIVA Research Chair)
- Philip Goodney, MD
- Juan Granada, MD
- Michael R. Jaff, DO
- Sanjay Misra, MD
- Christopher White, MD

VIVA'S CURRENT RESEARCH PROJECTS

Research Chair: Krishna Rocha-Singh, MD

Patient-level data meta-analysis focused on safety of DCB/DES (2019)

Following the publication of the Katsanos meta-analysis, which found an increased risk of mortality following the use of paclitaxel-coated balloons and stents, VIVA Physicians took the lead in a pan-industry collaboration to pursue a re-analysis of safety using de-identified, patient-level data. This effort will be led by a multidisciplinary Steering Committee and a statistical consultant with expertise in meta-analyses. The Steering Committee will select an independent third-party statistical group to assist in the re-analysis. VIVA is committed to a transparent, timely, and comprehensive analysis of these data.

ICON Study: Critical Limb Ischemia Study (2019)

VIVA is currently developing a study that will evaluate the effects of standardized recommendations of 'best practices' for the care of patients with Critical Limb Ischemia which will include medical, interventional and wound care, including app-based wound volume assessment when compared to local standard of practice. The study will evaluate the potential impact on both hard clinical endpoints and health economics. The study will follow up to 1000 patients through 18 months drawn from 30 geographically diverse practice settings.

Calcium score analysis (2018-2019)

VIVA has undertaken a Vascular Calcification Index Scoring Initiative to identify and classify predictors of independent core lab adjudicated acute and late outcomes following DCB use in the femoropopliteal artery. An independent statistical group will use patient-level, de-identified demographic and angiographic data sets from several large DCB studies to assess predictors using a novel calcification scoring system. This study of over 1,100 patients followed through 12-months will ultimately improve our understanding of DCB use in calcified femoropopliteal arteries.

Directional atherectomy / DCB outcomes (2017-2019)

The VIVA-sponsored REALITY trial investigates patients with significantly calcified, symptomatic femoropopliteal disease following HawkOne™ directional atherectomy device and IN.PACT™ Admiral™ drug-coated balloons. Using core lab and duplex ultrasound adjudication, REALITY assesses safety and duplex-Doppler vessel patency through 12 months. The study, which includes international sites, will enroll its final patients in Spring 2019. The study is managed by VIVA, with Drs. Rocha-Singh and Brian DeRubertis serving as PIs and is funded by a research grant from Medtronic.