ROUNDTABLE DISCUSSION

Paclitaxel in PAD: Where We Stand

A panel discussion on the current state of paclitaxel in peripheral artery disease, including how device use has changed, conversations with patients about safety and informed consent, key lessons learned, and how to move forward.

WITH DANIEL J. BERTGES, MD; THEODOSIOS BISDAS, MD; BRUCE H. GRAY, DO, FSCAI, MSVM; RAMON L. VARCOE, MBBS, MS, FRACS, PHD; AND SABINE STEINER, MD; WITH ADDITIONAL COMMENTARY BY JOS C. VAN DEN BERG, MD, PHD

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How would you briefly summarize where the vascular interventional community stands with respect to the use of paclitaxel-based devices for peripheral artery disease (PAD) therapy?

Dr. Bertges: With more study and follow-up, we have seen an attenuation of the mortality signal in the randomized trials. Notably, large observational data sets have not detected the signal. However, uncertainty remains. Understandably, the benefit of reduced reintervention has not received as much attention. At present, it comes down to an individual decision between the doctor and the patient.

Dr. Gray: Since the initial publication of the meta-analysis of Katsanos et al in *Journal of the American Heart Association* (*JAHA*),[1] the response of the vascular community has been incredible. Industry has reviewed, revised, and pushed out data like never before. Publications and podiums have been saturated with debates from each side as to the significance of the long-term mortality signal. Some hospitals have removed the devices from their shelves, whereas others have only slightly altered their use. The FDA has provided a warning without conviction (they did not institute a moratorium) as to the potential strength of the mortality concern. It is fair to say that there is a lack of consensus as a vascular community; few minds have been moved from their bias, and physicians are left to describe a controversy that has no definitive answers at this time.

With that said, use of paclitaxel-coated devices continues because drug-coated balloons (DCBs) and drug-eluting stents (DESs) provide longer primary patency compared to their nondrug-coated comparator. So, the impact that paclitaxel has on reducing restenosis has remained unchallenged since the publication of the meta-analysis. Paclitaxel-containing devices are also more expensive, and their use is limited in certain environments (eg, office-based labs). The perceived value of these devices based on net cost hasn't changed. Lastly, very few patients are aware of the controversy and therefore do not have a predetermined bias.

Prof. Varcoe: When the *JAHA* meta-analysis came out in December 2018, most people were shocked at the thought of a drug like paclitaxel causing harm. Most of us had an immediate reaction and decided to avoid using paclitaxel-coated devices while we gained a better understanding of what the signal meant. However, as time elapsed and more information came to hand, most experts became skeptical of the *JAHA* findings. This was because there was no plausible biologic mechanism or a link between mortality and dose or spike in any specific cause of death that might support a toxicity theory. As new evidence has come to light—in the form of large-scale, real-world studies, more randomized controlled trials (RCTs) with longer follow-up, and additional meta-analyses—most people have returned to using paclitaxel-coated devices because of the additional durability and, subsequently, the reduced need for invasive revascularization procedures they provide for our patients.

Dr. Steiner: Almost 2 years after the *JAHA* meta-analysis indicated an increased mortality in patients receiving a paclitaxel-coated device for femoropopliteal interventions,[1] we have seen an unprecedented collaboration between researchers, professional societies, regulatory agencies, and the device industry in exploring this signal based on data from RCTs. Importantly, patient-level analyses with enriched follow-up data weakened this mortality signal. Extensive observational data could not corroborate it either—rather, they refuted it. So far, no causal relationship or dose dependency could be established between paclitaxel exposure and mortality, despite multiple efforts. Because paclitaxel-based devices are still under scrutiny, the vascular interventional community faces the ongoing challenge of weighing risk versus benefit in individual patients.

Dr. Bisdas: The meta-analysis by Katsanos et al[1] led to a unique debate among vascular specialists, which we may never see again in our community. The supporters of this paper found a clear signal of higher dose-dependent mortality of paclitaxel-coated devices because this outcome was based on RCT data. However, several physicians claimed that this result was a statistical "illusion" due to an unpowered analysis. Their statement was supported not only from numerous industry-driven, individual, patient-based analyses but also from retrospective large cohort analyses.

The most comprehensive individual patient-level data analysis was completed by VIVA Physicians in collaboration with FDA, leading clinicians, researchers, and statistical analysts. This study identified a weaker mortality signal than was initially reported by Katsanos et al (absolute 4.6% increased mortality risk associated with paclitaxel use) but without any drug-dose relationship.[1,2] Considering that this analysis includes claudicants with short lesions, we still have a significant evidence gap regarding the impact of paclitaxel in claudicants with long and complex lesions or patients with chronic limb-threatening ischemia (CLTI). At the moment, paclitaxel use is recommended in lesions at high risk for restenosis, regardless of length, complexity, or clinical status of the limb.

How has your use of paclitaxel-coated devices changed in the past 2 years and why?

Prof. Varcoe: My use of paclitaxel-coated devices is largely unchanged. We have published two subsequent meta-analyses that show no link between mortality and paclitaxel use in patients receiving treatment for dysfunctional dialysis access and critical limb ischemia (CLI).[3,4] Therefore, we use paclitaxel without hesitation in those groups. The only patients for which I still retain a question mark are very young claudicants with good venous conduit who would require several drug-coated devices to treat their disease. These patients may be better suited for venous bypass surgery.

Dr. Steiner: Treatment with paclitaxel-eluting devices has repeatedly exhibited a clear clinical benefit for patients undergoing femoropopliteal interventions with respect to improved patency rates and reduced need for target lesion revascularization. Based on German and international recommendations, patient communication about the benefit-risk profile of paclitaxel devices has become a central topic in conversations with patients. Many of our patients are considered high risk for restenosis based on anatomic features such as long occlusions, in-stent restenosis, poor runoff, and small vessel diameter or as a consequence of polyvascular disease with multiple previous vascular interventions and comorbidities. Therefore, we believe that the benefit of paclitaxel-coated balloons and stents outweighs potential risks in most cases, and the use of paclitaxel-containing devices still represents a cornerstone of interventional therapy for femoropopliteal disease in our daily routine.

Dr. Gray: I remain a strong advocate for the use of these devices in lesions in the femoropopliteal segment because the data show that paclitaxel reduces restenosis and the need for reintervention. The VIVA Physicians analysis of patient-level data failed to show a dose effect or a mechanism or means for increased mortality, and therefore a direct causal relationship between paclitaxel and long-term mortality was not found.[2] The Medicare Advantage analysis[5] did not show a mortality signal as was seen in the meta-analysis by Katsanos et al.[1]

I use paclitaxel-coated devices liberally in elderly patients with CLI and long lesions and curtail the use in young patients with mild disease that can be easily treated without drug. It is my treatment of choice for 4-mm superficial femoral artery/popliteal lesions and, especially, restenotic lesions. In lesions with heavy plaque burden, DESs are preferred to minimize recoil, along with intimal hyperplasia.

Dr. Bisdas: After the publication of the first meta-analysis,[1] we stopped using paclitaxel-coated devices for a short period, mainly due to the potential legal issues. After the publication of the independent patient data and the larger retrospective series, we restarted our paclitaxel-coated devices program following the FDA recommendation. At present, we routinely use our paclitaxel-coated devices as we did before, but we inform our patients about the potential risks of using and not using paclitaxel as a final treatment strategy.

Dr. Bertges: Personally, I reacted quite aggressively to the meta-analysis by Katsanos et al.[1] Almost immediately, I stopped offering paclitaxel-coated devices to my patients. As more became known and subsequent to the FDA panel, I made paclitaxel-containing device selection part of my "enhanced" informed consent for highly selected patients with CLTI. Today, I consider using these devices for patients with CLTI, claudicants with longer lesions, popliteal lesions across the knee, and recurrent disease.

How would you describe your conversations with patients regarding paclitaxel-coated device use for their femoropopliteal disease during the time since the initial publication in *JAHA*?

Dr. Bisdas: The main question that all patients ask during the informed consent is about the exact groups of patients at higher risk of death after paclitaxel use. At present, we are not able to answer this important question. On the other hand, the patients do receive a clear answer regarding the high risk of restenosis after not using paclitaxel. I have not yet had a patient forego receiving paclitaxel-coated devices.

Dr. Steiner: What has changed as a positive impact from the ongoing dispute is the way we discuss treatment strategies with patients. The focus on physician-patient communication has been extended from lesion-centered outcomes, such as patency rates, to long-term prognosis of the patient, including PAD progression, cardiovascular morbidity, and even total mortality.

Dr. Bertges: The paclitaxel signal has forced me to reconsider the informed consent process for peripheral vascular intervention. Admittedly, I never discussed my device selection with patients in the past. Now I do. The discussion is longer, and I usually find that the decision takes two conversations for me to be reassured that the patient understands the complexity of the issue. I focus even more on how to fairly present risk versus benefit.

Going forward, I hope to implement some graphics on decision support to use in patient preference research. I suspect a visual depiction of risk can augment the discussion. This rethinking of consent has been a positive outcome of the debate.

Prof. Varcoe: Initially, there was a real drive toward full disclosure during the informed consent process. However, it quickly became apparent that most patients were unable to grasp the finer details of the statistical signal and what it meant. In truth, most vascular specialists were also having difficulty understanding what the signal meant. Ultimately, the majority of patients put the decision-making responsibility back onto physicians and asked the physicians to decide what was best for them. The signal became even more difficult to explain as conflicting evidence began to appear that casted significant doubt over the results of the first meta-analysis. Currently, I tell patients that there is a single study that has observed a link between paclitaxel and mortality. It is unclear what this means, and further study is ongoing. It currently remains controversial, but what is not controversial is that these treatments reduce the need to come back for future angioplasty procedures.

Dr. Gray: The paclitaxel controversy is very difficult to describe even to the most sophisticated patients. I mention the use of drug coatings in general terms and share some of the data surrounding the decision, but I usually acquiesce to the bottom line that I will think and act in their best interest. Procedural decisions are influenced by individual patient demographics, degree of ischemia, and anatomic challenges. No data summarized in any study can provide a universal prescription for every patient. I try to develop a trusting relationship with patients, and I emphasize that we are not just treating a "blocked artery" but providing comprehensive care.

What has been one key lesson you have personally learned throughout the paclitaxel controversy—something you have changed your mind about or have come to understand much better during this time?

Dr. Steiner: As a clinical trialist, I've been impressed by how much bias and confounders—that are obviously poorly understood—might influence important outcomes in both control and active (ie, paclitaxel-based) treatment arms. Obtaining long-term, patient-centered outcomes in parallel with minimizing loss to follow-up are definitely crucial for the success of future trials in the field.

Dr. Gray: I used the word "incredible" previously to describe the response of the vascular community to the original meta-analysis published by Katsanos et al. These authors ignited a fire storm response to their work.

The New UK/Europe IFU and Discussions With Patients

With Jos C. van den Berg, MD, PhD

In June 2020, United Kingdom and European Union agencies posted a Field Safety Notice stating that a warning and summary of the Katsanos et al meta-analysis[1] published in *JAHA* in December 2018 will be added to the indications for use (IFU) of 12 paclitaxel-coated balloons and stents used in the treatment of lower extremity PAD throughout Europe. According to the notice, the updates should also be supplemented with clinical data specific to each device concerned (eg, Kaplan-Meier mortality estimates at 2, 3, and 5 years for that treatment device versus the control device).

What has been your experience to date in discussing the new IFU and informed consent for paclitaxel products with patients?

I had already started discussing the issue raised by the *JAHA* meta-analysis with patients after the results of the FDA panel were available—even if I am personally still not convinced that there is an additional mortality risk after seeing all the large Medicare and German insurance database analyses.[2-4] Also, the recent paper by Böhme et al is very reassuring in this respect.[5] This discrepancy between my personal interpretation of all data published thus far and the data that were used to formulate the new European rules (which were only based on the devices included in the meta-analysis and those discussed in the FDA panel) makes it very difficult to discuss the issue. This is a factor for physicians in Europe because there are many other different devices available at the moment that were not taken into account in the *JAHA* meta-analysis and FDA panel.

How do you address uncertainty as to which device you might use during the actual procedure if you are unsure at the time of consenting the patient? Similarly, how do you adjust for differences in the available data by device?

I am never sure up front which device will be used, and I also think that it is too much to present a complete review of the literature, with every outcome of each of the different devices, to a patient. This is truly information overload in my opinion. Therefore, I use the mean percentages for both mortality risk and target lesion revascularization as the guideline in my discussion with the patient, even though I know that most patients I treat have longer and more complex lesions than those that were included in the randomized trials and therefore will be at higher risk for restenosis.

How have patients responded to the new IFU/informed consent?

The most frequent answer is, "Doctor, you should do what you think is best for me."

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3. Freisinger E, Koeppe J, Gerss J, et al. Mortality after use of paclitaxel-based devices in peripheral arteries: a real-world safety analysis. Eur Heart J. Published online October 8, 2019. doi: 10.1093/eurheartj/ehz698
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5. Böhme T, Noory E, Beschorner U, et al. Evaluation of mortality following paclitaxel drug-coated balloon angioplasty of femoropopliteal lesions in the real world. JACC Cardiovasc Interv. Published June 18, 2020. doi: 10.1016/j.jacc.2019.02.020

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Although they did not provide any definitive answers, they stimulated thought, forced collaboration, asked questions that were not asked before, and acted as a patient advocate in their deliberations. This wasn't even an RCT, but the impact has been dramatic. So, this type of influence is open to us all if we continually try to ask and answer questions. We need to be able to articulate why we do what we do and be held accountable for those decisions. The peripheral literature falls woefully short. We need to be able to better explain, explore, and

expand our evidence base. We need to bridge this gap both individually and corporately. Our obligation to the patient begins well before any treatment decisions are made and extends well beyond the conclusion of the procedure.

Dr. Bertges: Lately, I have been reading the works of Nassim Nicholas Talib, who writes with a unique perspective on risk, secondary order effects, and iatrogenic complications in medicine in *Antifragile: Things That Gain From Disorder*. This has reminded me of the adage, "First, do no harm." I have been reminded how little we know. I'd also like to offer a second lesson from science that is playing out in real time with the coronavirus pandemic. Science and our understanding evolve. Peer review and open discussions of the strengths and weakness of various methodologies is a process.

Dr. Bisdas: None of us imagined that paclitaxel would lead to safety issues and concerns about mortality. Quite surprisingly, however, the evidence revealed a mortality signal. This finding should be a lesson for every physician to be more cautious with implementing a new device or technology if there is no strong evidence to support its safety and effectiveness. Moreover, it is a combined responsibility of the involved medical societies and physicians to run real-world registries to prevent similar phenomena in the future.

Prof. Varcoe: I think we have all gained a better understanding of clinical trial design and the importance of minimizing bias, particularly the ascertainment bias that comes from having large proportions of patients who are lost to follow-up or whose data are missing. This phenomenon has been demonstrated unequivocally and has clearly played a large role in the signal observed by the original meta-analysis.

Is paclitaxel likely to remain the primary drug on peripheral devices, or will other options such as sirolimus displace it? Will the barrier to entry for other agents be affected by the paclitaxel controversy?

Dr. Gray: The biology of restenosis remains a vexing problem, and although paclitaxel helps to reduce intimal hyperplasia, it is not the final answer—nor is sirolimus. Acquiring 5-year endpoint data for subsequent devices/drugs/delivery systems will be costly and time-consuming. The next entry into the market must have dramatic short-term impact (positive, significant benefit seen in as few as 100 patients) to justify the cost and investment in long-term study.

Advancements in our understanding of biology, biomedical engineering, immunology, and genetics will dramatically alter treatment options in the future. With this in mind, I think the next antirestenotic strategy will involve nanoparticle delivery. These small carrier molecules can be conjugated with antibodies targeted to specific proteins. This strategy may provide more of a silver bullet rather than a shotgun blast in the war against restenosis. There will also be a more directed attack against calcification using nanoparticle chemical technology. The targeted dissolution of calcium deposition, particularly in our diabetic population on dialysis, will move us beyond our preoccupation with luminology by treating more of the disease processes in the artery.

Dr. Bisdas: The current body of evidence proved a clear superiority of paclitaxel-coated devices in the infrainguinal vessels compared with uncoated balloons or stents concerning restenosis. I think that many physicians will try to replace paclitaxel with sirolimus-coated devices based on the argument of mortality, but this is wrong. We first have to confirm the efficacy of sirolimus regarding both patency and safety in the framework of RCTs. Regarding the second question, the current paclitaxel controversy will not be a barrier to entry for other agents because the alternative of uncoated devices has already shown poorer performance in all prospective studies.

Prof. Varcoe: This is an interesting question. The challenge with sirolimus-coated devices has been an engineering one: how to provide a stable coating with good drug wall transfer and reservoir deposition. There are several manufacturers who tell us they've now found a solution to those challenges, but the proof will be in the clinical results from large-scale, well-conducted RCTs. Those new devices have a long way to catch up to the large body of literature that exists for the use of paclitaxel-coated balloons and stents. However, because safety remains paramount, it is possible that if these devices are found to be noninferior, they could come to be preferred over paclitaxel.

Dr. Bertges: Technology is ever-changing, and we operate under the assumption that new is always better. I assume that an alternative will emerge over time. The barrier to entry will be greater but surmountable. I firmly believe future device evaluation will be strengthened by the paclitaxel experience. Numerous groups, including individual specialty societies, such as the Multi-Specialty and Multi-Society Coalition for Patient Safety with Paclitaxel-Coated Endovascular Devices and the Registry Assessment of Peripheral Interventional Devices (RAPID),

are working on the lessons learned from the paclitaxel signal. Harmonization of covariates and outcomes into a consensus case report form, active risk-adjusted post-market surveillance in registries, and comprehensive late follow-up are a few of the positive responses that may come from this controversy.

Dr. Steiner: Although we have promising preliminary data from studies investigating sirolimus-coated balloons and stents for femoropopliteal disease, it will be years before we can expect results from direct head-to-head comparisons between paclitaxel- and limus-based devices. These results are needed to make clear recommendations of one drug over another. As we have learned so much about clinical trial design and conduct over the last few months, this knowledge set the bar for the introduction of new technologies in the field. In addition, a new regulatory framework for medical devices is underway in Europe, and device evaluation will face increased scrutiny in general.

In your opinion, how do we definitively move beyond this controversy?

Dr. Bisdas: The current recommendation that paclitaxel should be used in patients at high risk for restenosis is the way to move beyond this debate. In my opinion and taking into consideration the importance of vessel preparation, any lesion undergoing adequate vessel preparation can be defined as high risk for restenosis. Thus, paclitaxel should be used without any doubt in the treatment of almost all femoropopliteal lesions. At the same time, any new trial using paclitaxel or any other agent should be powered enough from the statistical point of view to confirm safety and efficacy.

Prof. Varcoe: It is my view that we need additional RCT data at those longer time points, out to 5 years. With additional numbers and minimization of missing data, I'm confident that we'll see this signal become diluted and eventually disappear.

Dr. Bertges: I am not sure we will ever get an "all clear" on this controversy, but I think it will take an unambiguous statement from regulators. Clinicians, industry, and regulators are working hard to reconcile the various data sources. Short of regulatory clarity, market forces will decide the future of these devices.

Dr. Gray: Further analysis of data derived from previous studies will not provide answers to the current controversy. Paclitaxel will remain in question. It remains to be seen what suitable alternative drugs, solvents, or chemicals can be of benefit. The cost of developing these alternatives will increase substantially because long-term follow-up will be mandated. This significance must be demonstratable with relatively few patients to justify the cost. Therefore, with low patient numbers, the clinical difference (or delta) must be dramatic.

Dr. Steiner: So far, I don't see a quick ending for the dispute, but I believe that over the next few years, ongoing research will shed further light on the existence and potential magnitude of the late mortality signal. Step-by-step, we will gain more confidence in our judgment, allowing us to update benefit-risk considerations. The discovery of a comprehensive causal relationship between paclitaxel and mortality would be a game changer, but so far, this is not on the horizon.

What is the biggest remaining issue to be addressed before we can move beyond the controversy?

Dr. Bertges: We need to reconcile the mortality signal reported in the unpowered randomized trials with the large observational data sets. This is simultaneously a challenge and an opportunity for real-world data.

Dr. Bisdas: In my opinion, two issues need further clarification: (1) the efficacy and safety of paclitaxel in long lesions and in patients with CLTI and (2) the toxicity of paclitaxel on the vessel wall that causes extensive positive remodeling or even aneurysm. The latter was highlighted in our paper published in *JACC: Cardiovascular Interventions*.[6]

Dr. Gray: The potential "risk" of paclitaxel must be balanced against the potential "reward" for the patient when used with or without stenting. We have limited comparative data between DCBs, DESs, and brand variation. Not all provide the same "reward," and I doubt that they all provide the same "risk." We have lumped all devices into the same category, making the decision process extremely challenging. I choose not to throw the baby out without first knowing the true temperature of the water! ■

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