

## PANEL DISCUSSION

# Pelvic Venous Disorders: Practice Realities

Top priorities for research, industry's ideal role in supporting PeVD initiatives, real-world challenges in practice, key equity issues and actionable next steps, and top components of a multidisciplinary team.



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## What areas of pelvic venous disorders (PeVDs) research are your top priorities?

**Dr. Harth:** A significant amount of work and research is needed in the field of PeVDs. To provide perspective, CEAP (clinical, etiology, anatomy, pathophysiology) classification was first introduced in 1996, was subsequently revised in 2004 and 2020, and is the main classification system used in the latest 2020 appropriate use criteria for chronic lower extremity venous disease. In 2021, the SVP (symptoms, varices, pathophysiology) classification was published and is the first classification system for venous conditions of the abdomen and pelvis. Up until 2021, research and clinical management have largely lacked standards and a framework to allow uniformity among evaluated patients. This certainly creates challenges in how to approach these patients, how to interpret the literature, and, importantly, how to best manage them. The research priorities are many, but I think three important areas to focus on include (1) defining appropriate diagnostic testing protocols that incorporate venous-specific maneuvers, (2) performing clinical trials and/or registries of currently available therapies using SVP classification designation, and (3) defining the important outcome measure/variables for each disease-specific state.

**Dr. Jaworucka-Kaczorowska:** There is still much work to be done in the field of PeVD. Understanding the causes and mechanisms of PeVD is crucial. It is still unclear which patients with pelvic venous insufficiency (PVI) will develop symptoms and why, or whether PVI is merely an asymptomatic comorbid condition. There is a lack of a generally accepted, well-defined clinical scoring system and well-established imaging criteria for diagnosing PeVD and selecting patients who would benefit most from the intervention. Venous dilation and venous reflux are not sufficient to lead

to both symptoms and a diagnosis of PeVD. Incompetent and dilated ovarian veins can be found in almost 50% of asymptomatic women, as can pelvic varicose veins, especially after a second pregnancy.<sup>1</sup> In addition, 90% of patients have no valves in the internal iliac vein.<sup>2</sup> Asymptomatic common iliac vein and left renal vein compression causing  $\geq 50\%$  reduction in area can be found in 25% to 33% and 51% to 72% of the general population, respectively.<sup>3,4</sup> A scoring tool for PeVD is currently being developed through different societies but is not available yet.

Research should also be focused on evaluating and optimizing treatment options for PeVD. This includes studying the effectiveness of minimally invasive procedures as well as conservative management, which is often overlooked. The problem is the heterogeneity of PeVD. Well-conducted randomized controlled trials (RCTs) that include homogeneous study populations proving the efficacy of intervention and comparing different treatment modalities are still awaited. Comparative studies assessing the long-term outcomes, safety, and cost-effectiveness are important for guiding clinical decision-making.

**Dr. Winokur:** Advancement in the understanding of PeVD has been needed for some time based on the absence of RCTs, leading to limitations in insurance coverage for these procedures despite data demonstrating clinical improvements following intervention. The research consensus panel published in 2019 by Khilnani et al delineated several priorities for advancement in the understanding of this disease process to allow for patient improvement.<sup>5</sup> One major priority was the development of a classification scheme, which was published in 2021 by Meissner et al and is an important tool for use in clinical trials and daily practice.<sup>3</sup> Another major challenge is identification of the correct population with venous-origin chronic pelvic pain (VO-CPP). Development of diagnostic criteria is currently underway and will be a critical element to allow for identification of clear clinical symptoms that correlate with VO-CPP, allowing for differentiation of patients that may benefit from intervention.

Randomized controlled data collection to prove the efficacy of intervention in these patients is also strongly needed. The EMBOLIZE trial, a randomized, placebo-controlled trial of ovarian and pelvic vein embolization in women with CPP and pelvic varices, is soon to finalize funding and will be initiated at multiple centers. This study will produce clear outcomes data to validate the disease-specific quality-of-life tool that is being created and will allow for further understanding of pain variation over time and in relation to specific activities. It will also allow for better understanding of imaging tools that are used to identify pelvic venous pathology and varices. In addition to

studying ovarian vein embolization (OVE), similar research into iliac vein stenting for nonthrombotic iliac vein lesions (NIVLs) is critically important. Improved understanding of a clear definition of compression will lead to improved usage and prevent overuse of iliac vein stenting for NIVLs.

### What is the ideal industry role in supporting initiatives for PeVD research and growth of the field?

**Dr. Winokur:** Industry frequently performs clinical research and has helped in the advancement of several devices and procedures in the venous intervention space. Because PeVD interventions are currently considered investigational by many insurance companies, industry support to improve disease understanding and optimal interventional strategies will be very important to move the needle forward in the near future. It is important for industry to partner with individuals and societies that are driving the upcoming research studies to allow this change to occur for patients.

**Dr. Harth:** Industry has an important role to play in PeVD initiatives. One important area includes supporting investigator-initiated multicenter trials evaluating available therapies in studies with sound study design. A particular highlight is support for studies evaluating treatment of patients with CPP due to gonadal vein reflux. The inconsistent study designs and results from past studies have largely failed to show definitive evidence of treatment efficacy. This has negatively affected coverage policies for gonadal vein embolization and thus denies most women a therapy that most venous providers feel has more benefit than risk to be gained in the appropriately selected patient. To achieve equitable access to PeVD therapies, industry should prioritize studies that focus on study designs that will ultimately improve access to care and influence policy to improve coverage.

**Dr. Jaworucka-Kaczorowska:** Industry can play a key role in supporting initiatives for PeVD research and development. One of the most important aspects is raising public awareness and educating patients and health care professionals about these disorders. Industries can also support research initiatives by providing grants and funding opportunities for researchers, which can include conducting clinical trials and facilitating the translation of scientific discoveries into clinical practice.

Industry's help can be crucial to improving the diagnostic and treatment process. They can collaborate with researchers and clinicians to develop electronic medical record systems that include specific templates or modules for PeVD, standardized worldwide, or create specialized

diagnostic questionnaires, imaging protocols, and outcome measurements. They can also contribute to optimizing existing treatments and developing and producing innovative medical devices specifically designed for PeVD that enhance diagnostic and treatment options and improve patient outcomes.

Industry's role may include actively participating in phlebology society meetings and conferences on PeVD and contributing to the development of educational programs and workshops.

It is worth noting that collaboration, as well as close partnerships between health care professionals, researchers, and industry, is crucial for achieving significant progress in the field of PeVD. By working together, these stakeholders can accelerate research, improve diagnostic capabilities, and develop more effective treatments for patients.

### **What are the most significant real-world challenges you face in your practice? How might they be overcome or resolved?**

**Dr. Jaworucka-Kaczorowska:** The biggest challenge I'm facing in my practice regarding patients with PeVD is the correct diagnosis and appropriate qualification for treatment, especially in patients with CPP. CPP is a symptom with multiple potential etiologies and very often results from overlapping disorders of the reproductive tract, gastrointestinal system, urologic organs, musculoskeletal system, and psychoneurologic system, which each contribute to pain. PeVD has been reported as a possible cause of pain in 16% to 31% of women with CPP.<sup>6</sup> On the other hand, most patients with PVI are asymptomatic and do not require any diagnostic evaluation and treatment at all. It is still unknown which patients will develop symptoms and why, whether the symptoms of the patient are related to PVI, or whether PVI is only an asymptomatic comorbidity. Therefore, implementing standardized diagnostic protocols and interdisciplinary collaboration among specialists (eg, vascular surgeons, interventional radiologists, gynecologists) is essential and can improve the accuracy of diagnosis and effectiveness of treatment.

**Dr. Harth:** Being able to offer innovative and contemporary therapies to patients with PeVD is one of the many exciting things about being in this field. But, being able to offer therapies only counts if patients come to you for an evaluation. A significant obstacle to making that happen is lack of education in venous disease among referring providers. Unfortunately, venous disease has historically not been an area of focus in medical education, which has created generations of physicians who generally lack understanding of venous disease conditions, how to rec-

ognize them, and how they can be managed. As venous specialists, we have several opportunities to contribute to improving this deficiency through efforts at the local and national level. If we want future generations of physicians to be better educated, then we can certainly start with our students and trainees and provide them exposure to comprehensive venous disease education through lectures, rotations, research involvement, and engagement in our societies. We can also similarly provide educational opportunities to physicians and advanced practice providers to help educate them on proper identification of various disease states and referral patterns. There are also specialty-specific biases regarding the validity of PeVD as contributors to certain clinical presentations that must be overcome as a medical field. For this, in addition to the aforementioned, I think developing collaborations across specialties helps open opportunities for knowledge sharing.

**Dr. Winokur:** The major challenges that occur in PeVD include appropriate clinical referral and identification by the gynecology community, optimal patient selection criteria to predict patient benefits from intervention, and insurance coverage for OVE. All of these challenges are intertwined, as the limitations in coverage and proven outcomes have created doubt about ovarian vein insufficiency as a major cause of CPP by both insurers and gynecologists. The major efforts being planned for research to advance the understanding of the disease process and proven outcomes of interventions will assist in overcoming these challenges.

### **What equity issues need to be addressed, and importantly, how can/will they be? What are the key next steps?**

**Dr. Winokur:** The imbalance of insurance coverage by gender for similar pathology is a major issue that needs to be resolved. Because varicocele embolization is generally covered while OVE is often considered investigational, progress needs to be made to acknowledge the importance of VO-CPP. Advancement of key research protocols and priorities will help address the inadequate data leading to these insurance coverage challenges. In addition to funding and initiating critical RCT data collection to prove the value of OVE, further efforts to change the coverage limitations will be needed once these research studies are completed.

**Dr. Jaworucka-Kaczorowska:** Addressing equity issues in the context of PeVDs is essential to ensure that all individuals, regardless of socioeconomic status, race, ethnicity, gender, or geographic location, have equitable access to

accurate diagnosis, appropriate treatment, and supportive care. It can be achieved through increased awareness and education, empowerment of patient advocacy groups, and support networks. This includes developing educational materials in multiple languages, culturally appropriate outreach programs, and campaigns to improve understanding of the condition's signs, symptoms, and available treatment options. Collaboration with patient advocacy organizations can help identify and address specific needs and barriers faced by PeVD patients.

The equity issues also apply to health care professionals treating PeVD. Although PeVD mainly affects women, these patients are still usually treated by men. This topic is also mainly addressed by male speakers at scientific meetings, as well as in panel discussions on PeVD. This can exacerbate barriers between female patients and doctors, especially because it is a disorder that affects very intimate areas. It is often a very embarrassing problem for women, especially when it involves the vulvar region as varicose veins of pelvic origin. The next key step in management of PeVD is to involve more female health care professionals, which can make it easier for female patients to access PeVD diagnostics and treatment.

**Dr. Harth:** Equity issues that stand out at this time in my practice relate to (1) near-universal lack of coverage for gonadal vein embolization for women with VO-CPP and (2) lack of equity in access to venous care among diverse populations. Some key next steps to address these issues relate to the previous discussion of research and education. Additionally, I think advocacy also plays an important role in this process, as we need to educate the public and patients on these issues because they too are a crucial part of the process of achieving progress.

### **What is your approach to educating other providers about PeVD? What advice do you have for how to go about starting or enhancing a PeVD practice and providing excellent care?**

**Dr. Winokur:** Women with CPP often are seen and managed by multiple providers from different specialties who may have mixed acceptance of a venous origin for CPP. Partnership with other specialists can be challenging, but many gynecologists, physiatrists, and pelvic floor physical therapists are open to addressing venous sources of CPP to improve patient symptoms. When communicating with these other providers, it is important to be honest about the current state of knowledge and understanding of this disease process and that work is being done actively to advance research and value of venous interventions. Once that multidisciplinary partnership is formed, providers will be more willing to refer patients for evaluation and

possible intervention. Another important point is not to assume that all referrals for evaluation will or should lead to procedural interventions. Some referrals will not have VO-CPP, and our role as interventionalists is to exclude that possibility.

**Dr. Harth:** There are several ways I have engaged the process to increase PeVD education. All of these strategies involve time commitment and support. Educational lectures can be given in various forums such as lunch-and-learn sessions, dinners, visiting local group practices to provide educational materials and introductions, grand rounds, and patient-focused webinars. Certainly, this process is another great area where industry can support physicians in their educational endeavors. In choosing the most effective way to approach this, one could consider focusing on addressing groups that see the types of patients you can evaluate and potentially treat. Additionally, through our venous center, we have monthly “open virtual door” multidisciplinary educational conferences, which is a unique way to bring varied groups of physicians and trainees together to engage in primarily case-based discussions on PeVD. Importantly, in order to provide excellent care and education, it is important to do continual self-learning to stay on top of this very fast-moving field. I find that national meetings and venous-specific virtual educational opportunities are highly valuable in this process.

**Dr. Jaworucka-Kaczorowska:** It is very important to educate other health care providers about PeVD, as this disorder carries a heavy social burden. Based on a systematic review by the World Health Organization, CPP prevalence rates range from 4.0% to 43.4% based on 18 studies involving 299,740 women.<sup>7</sup> PVI accounts for up to 30% of cases. Unfortunately, only about one-third of women with CPP seek medical care, and only one-third receive proper diagnosis and treatment.<sup>8</sup> It is also a serious economic problem. Studies have shown that the total direct outpatient medical costs of CPP in women, as well as the costs of work time lost due to CPP, are very high.<sup>9</sup> The problem is not only CPP but also varicose veins of pelvic origin, which can occur in up to 25% of patients after previous varicose vein intervention.<sup>10</sup> Accurate diagnosis and effective treatment from the first presentation can reduce the endless series of referrals, investigations, and inappropriate treatment and can improve health-related quality of life, work productivity, and health care utilization.

My advice for how to go about starting or enhancing a PeVD practice and providing excellent care is to stay updated on the latest research, guidelines, and advancements in the field of PeVD. Regularly review relevant

scientific literature, attend conferences, and participate in practical courses focused on PeVD to improve your diagnostic and treatment skills. Collaborate with specialists in vascular surgery, interventional radiology, gynecology, and other relevant fields to enhance your understanding of PeVD, develop comprehensive treatment plans, and establish a strong referral network. This will ensure that you have the most current knowledge to provide excellent care and patients have access to comprehensive management when needed.

### How do you build a multidisciplinary team for PeVD care? What are the top three components to initiating one?

**Dr. Harth:** Find someone who is as passionate and interested in this patient population as you are and build an alliance! Also, identify someone with different skill sets to build partnerships with—this will often translate into patients benefiting from a higher level of combined technical expertise. Case sharing is an important component of fostering relationships with your PeVD team. This occurs at many levels and includes but is not limited to providing advanced practice providers the tools/knowledge to care for these patients and work collaboratively to properly select patients that would benefit from therapies; collaborating with procedural partners and performing complex cases together; and working and building the experience and exposure of your local vascular sonographers, who play a key role in the noninvasive evaluation of these patients. It is also important to realize that building this takes time, patience, and dedication. It does not happen overnight, and there are many lessons learned along this path, which is not always straight.

**Dr. Winokur:** Although pelvic venous hypertension may be a component of CPP, interventional strategies often do not completely resolve the patient's pain. If we look at the data on OVE, the visual analog pain score usually decreases to 2 to 3 points out of 10. Additional multidisciplinary treatment with pelvic floor physical therapy can often aid in continuing to improve patient symptoms. In addition to therapy and multidisciplinary care for these patients, it is important to partner with gynecology to exclude other common causes of CPP in advance of pursuing interventional strategies.

**Dr. Jaworucka-Kaczorowska:** Building a multidisciplinary team for PeVD care involves bringing together health care professionals from various specialties who can collaborate to provide comprehensive and holistic care to patients. In PeVD management, it means the collaboration of (1) vascular surgeons or phlebologists experienced in evaluating and treating vascular conditions,

including those affecting the pelvic region; (2) interventional radiologists skilled in performing minimally invasive procedures, such as embolization and stenting, which are commonly used in the treatment of PeVDs; and (3) gynecologists, who are usually the primary care physicians, can perform detailed transvaginal diagnostics, and can exclude other causes of CPP, the most common pelvic symptom of PeVD. It is also important to cooperate with other specialties, especially pain specialists or anesthesiologists, gastroenterologists, urologists, physiotherapists, and psychologists, as CPP is a symptom with multiple potential etiologies and very often results from overlapping disorders, which each contribute to pain.

It is essential to establish regular meetings or case conferences where team members can discuss complex cases, share insights, and collaborate on treatment plans. In addition to these components, it is crucial to involve other health care professionals, such as nurses, nurse practitioners, physician assistants, and support staff, in the multidisciplinary team. They play a vital role in coordinating patient care, providing education, and supporting patients throughout their health care journey. This team-based approach can improve patient outcomes, optimize treatment decisions, and provide holistic care for individuals with PeVDs. ■

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### Disclosures

**Dr. Harth:** Consultant to and speaker for Medtronic, Boston Scientific, GE, Inari Medical; speaker for Cook.

**Dr. Jaworucka-Kaczorowska:** Speaker for Alfasigma, Balton, Pierre Fabre, and Medi.

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