Members of SIR and ACP announce the formation of a work group to establish a definition/classification system for pelvic venous disorders.

BY KATHLEEN GIBSON, MD; NEIL KHILNANI, MD, FSIR, FACP; AND MARK MEISSNER, MD

Over the last several years, we have seen an increased awareness of the morbidity associated with pelvic venous disorders. The clinical spectrum of pelvic venous disorders includes chronic pelvic pain; vulvar and lower extremity varicose veins; pain in the perineum or a scrotal varicocele; lower extremity pain, edema, or venous claudication; flank pain with or without hematuria; or any combination of these symptoms. The complex anatomy of the abdominal and pelvic venous circulation is only beginning to be appreciated, and it is clear that symptoms may arise from reflux in the gonadal and internal iliac veins, nonthrombotic or postthrombotic iliac venous obstruction, or from compression of the left renal vein over the abdominal aorta. All forms of venous compression can also lead to secondary internal iliac or gonadal venous reflux.

Although there are numerous publications documenting successful intervention for pelvic venous disorders, imprecise disease definitions lead to heterogenous patient populations and, likely, suboptimal results. In addition, most studies of chronic pelvic pain in women have focused on venous reflux, with the importance of obstruction having only been realized recently.

Furthermore, the clinical endpoints have varied and frequently do not include meaningful assessments of patient improvements. This lack of standardization makes comparison between studies or pooled meta-analysis very challenging. Although well-constructed clinical guidelines are sorely needed in pelvic venous disorders, the heterogeneity of the data does not allow for strong recommendations. Despite this, the number of procedures performed to treat pelvic venous disorders, such as gonadal vein embolization and venous stenting, have increased dramatically. In order to optimize patient selection and outcomes of specific interventions, as well as ensure access to care for future patients, it is imperative to gather high-quality patient outcome data.

An International Pelvic Venous Work Group (IPVWG) has been organized and begun developing the evidence base with support from the Society of Interventional Radiology Foundation (SIRF) and the American College of Phlebology (ACP) Foundation. In October 2017, Dr. Khilnani led a research consensus panel in Washington, DC, which brought together radiologists, vascular surgeons, and gynecologists nominated by their societies, as well as a clinical trials expert from the United Kingdom, with experience with pelvic venous disorders to prioritize the important research questions in this area. The panel was funded by the SIRF.

The panel identified and began developing the necessary tools required before initiating clinical trials. These tools included (1) establishing evidence-based disease definitions, (2) developing discriminative tools to categorize the various forms of pelvic venous disorders (similar to the CEAP [clinical, etiology, anatomy, pathophysiology] classification system used for lower extremity venous
disease), and (3) creating validated disease-specific health-related quality-of-life outcome measures that can be used as a primary endpoint in clinical trials, including drug and device trials, to support labeling indications.

The IPVWG has developed concrete goals and timelines. As many of the proposed projects depend on accurate disease definition and classification, developing a discriminative classification scheme for pelvic venous disorders is the first priority. With this in mind, an international consensus meeting is planned for mid-July in Chicago, Illinois, organized by Dr. Meissner and funded by the ACP Foundation. The IPVWG has invited representatives from the ACP, SIR, American Venous Forum, the International Union of Phlebology, the European Venous Forum, the American College of Obstetrics and Gynecology, the Cardiovascular and Interventional Radiology Society of Europe, the International Pelvic Pain Society, and the Korean Society of Interventional Radiology, as well as organizations from Latin America and Asia to participate in development of the classification tool.

Concurrently, we have begun development of disease-specific, patient-reported outcome tools for pelvic venous disorders. Members of the IPVWG have been awarded a funding source grant from the SIRF to support this development. Karin Coyne, PhD, MPH, who was responsible for development of the Uterine Fibroid Symptom and Quality of Life questionnaire—a validated tool widely used to evaluate treatments of uterine fibroids—will be a coinvestigator on the grant.

Ultimately, we hope that rigorous development of these tools will lead to widespread adoption by clinicians and researchers. Such standardized and validated tools will allow us to gather the high-quality evidence needed to create guidelines for the diagnosis and treatment of patients with pelvic venous disorders.

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