Venous Disease: The Year in Review

An exploration of significant advances, challenges, and future directions in venous disease management.

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Venous disease is a significant cause of morbidity and mortality for patients of all ages, spanning from the impaired quality of life (QOL) associated with superficial venous disease to the high mortality associated with pulmonary embolism (PE). The past year has seen rapid progress in the approval and research supporting various devices and techniques used for the treatment of venous disease. The following discussion will cover the impact of recent trials, techniques, and devices that evolved in 2019 and will provide a look into the future of venous disease treatment.

DEEP VEIN THROMBOSIS: UPDATES ON TREATMENTS AND CLINICAL OUTCOMES

The cumulative incidence of postthrombotic syndrome (PTS) 8 years after an episode of acute deep vein thrombosis (DVT) may be as high as 30%.[1] The ATTRACT trial, published in 2017, failed to show a reduction in overall PTS with the addition of pharmacomechanical catheter-directed thrombolysis (PCDT) to anticoagulation as a first-line therapy in unselected patients with proximal DVT.[2] However, multiple secondary analyses of ATTRACT published in 2019 demonstrated the benefits of PCDT in reducing DVT burden, early leg symptoms, and PTS severity scores in patients with acute iliofemoral DVT. Further, a separate analysis demonstrated significant improvement in vein disease severity scores by placing cavo-ilio-femoral stents for venous occlusive disease.

Weinberg et al analyzed the 692 patients from the ATTRACT trial, assessing (1) the extent of residual thrombus and valvular reflux at 1 and 12 months after proximal DVT, and (2) PTS and QOL metrics at 24 months after PCDT.[3] In patients who underwent PCDT, Doppler ultrasonography findings at 1 and 12 months found significantly less residual thrombus (measured as noncompressible venous segments) in the common femoral veins (CFVs) and popliteal veins. Importantly, the authors found that decreased thrombus burden in the CFV at 1 month was associated with lower rates of PTS (61% in the control group vs 46% in the PCDT group; $P < .001$) and improved QOL (difference, 8.2 VEINES-QOL [Venous Insufficiency Epidemiological and Economic Study on Quality of Life] points; $P = .004$) at 24 months. Unfortunately, no similar association was found in the femoral and popliteal veins, and PCDT was not found to prevent valvular reflux.

A subgroup analysis of the ATTRACT trial performed by Comerota et al demonstrated that PCDT in patients with iliofemoral DVT resulted in reduced PTS severity, as measured by lower mean Villalta score and Venous Clinical Severity Score (VCSS) ($P < .01$ at 6, 12, 18, and 24 months), and fewer patients with moderate-or-severe and severe PTS.[4] Additionally, the authors demonstrated greater reductions in leg pain and swelling ($P < .01$ at 10 and 30 days) and improved venous disease–specific QOL (difference, 5.6 VEINES-QOL points through 24 months; $P = .029$) with PCDT.

Finally, Mabud et al retrospectively analyzed 406 patients to assess the safety and patency of lower extremity venous stents in treating thrombotic and nonthrombotic deep venous disease.[5] Primary, primary-assisted, and secondary patency rates at 5 years by Kaplan-Meier survival analysis were 57.3%, 77.2%, and 80.9%, respectively. In the subgroup analysis, the authors found that stent placement in the setting of acute thrombosis was associated with decreased 5-year primary, primary-assisted, and secondary patency rates

TOP HEADLINES IN VENOUS DISEASE

- **PCDT Shows a Demonstrated Benefit for Patients With DVT**
  Although PCDT does not decrease the occurrence of PTS, multiple analyses have shown its benefits, including improvement in short-term recovery from DVT, reduced progression of PTS severity in acute proximal DVT, and improved long-term QOL in patients with acute iliofemoral DVT.
- **Endovascular Venous Stent Reconstruction: Feasible, With Good Clinical Outcomes and Durable Patency Rates**
  Venous stent reconstruction has become the standard of care for chronic iliocaval thrombosis. Studies from the last 2 years have reported clinical success and good patency and have supported this treatment modality in a variety of clinical settings, including IVC filter–associated thrombosis, non-IVC filter–related chronic iliocaval thrombosis, and in pediatric patients.
- **FDA Approval of Dedicated Venous Stents**
  Venovo and Vici, two dedicated venous stents, received FDA approval in 2019. Studies of both stents indicate that they are safe to place and have patency rates and efficacy comparable to arterial stents.
- **Next-Generation Thrombectomy Devices Offer an Alternative to Thrombolysis**
  In clinical trials, next-generation devices had low rates of major bleeding and no documented occurrences of intracerebral hemorrhage. Compared to anticoagulation alone, they reported similar rates of clinical deterioration for PE and DVT.
- **Cyanoacrylate Closure Appears to Be Safe for Chronic Venous Insufficiency**
  Two studies comparing CAC with RFA for incompetent GSVs reported a lower mean procedure duration, a higher rate of complete occlusion, and fewer side effects for CAC.

compared with those placed for chronic thrombosis (62.5%, 81.2%, and 89.6% vs 77.6%, 90.4%, and 97.7%, respectively). Patients with inferior vena cava (IVC) stent placement (hazard ratio [HR], 2.11; $P < .0001$) or acute thrombosis (HR, 3.65; $P < .0001$) during the index procedure had a significantly increased risk of losing primary patency status. Villalta scores significantly decreased from 15.7 ± 8.6 before stent placement to 7.4 ± 6.5 after stent placement ($P < .0001$).

Why These Studies Are Important

Together, these study results demonstrate that although PCDT does not decrease the occurrence of PTS in terms of Villalta score, in unselected patients with acute proximal DVT (femoropopliteal and iliofemoral), PCDT may improve short-term recovery from DVT and reduce progression of PTS severity—while improving the long-term QOL in patients with acute iliofemoral DVT. Additionally, properly sized stents placed in the setting of chronic venous thrombosis result in satisfactory patency rates and improved Villalta scores. The results also indicate a lack of robust patient-centered outcome instruments for appropriate measurement of PTS. Although the Villalta scale has been the most widely used instrument for assessing PTS, it has many shortcomings. The results of the CaVenT trial[6] suggest that the Villalta score poorly reflects QOL, and other studies have suggested that the scale poorly accounts for the concerns of many patients with PTS, including agonizing discomfort, skin changes, fluctuating heaviness, and post-DVT concerns.[7] In addition, the Villalta score underidentifies patients with severe PTS.[8] A properly constructed and validated instrument is clearly needed to evaluate the impact of new therapies in preventing PTS.

INNOVATIONS IN VENOUS STENT RECONSTRUCTION PRACTICES

Thrombosis of the IVC is a commonly encountered problem and has many associated morbidities, including recurrent DVT, disabling lower extremity swelling, venous claudication, and venous ulceration. Endovascular venous stent reconstruction has become the standard of care for treating chronic iliocaval thrombosis, and recent studies have supported this treatment modality in a variety of clinical settings. Venous stent reconstruction may be safely performed in patients with IVC filter–associated thrombosis, non-IVC filter–related chronic iliocaval thrombosis, and in pediatric patients.

Although previous work has demonstrated high patency rates after iliocaval stent reconstruction in patients with IVC filter–associated thrombosis,[9] a recent study assessed stent patency and clinical outcomes in patients who underwent naive recanalization and stent reconstruction for chronic or acute-on-chronic non-IVC filter–associated iliocaval occlusion.[10] Using a combination of blunt (n = 59; 86%) and sharp (n = 10; 14%) recanalization techniques, the authors reported a 100% technical success rate. One (1.4%) major adverse

event (MAE) occurred during the study period. Clinical success (defined as a ≥ 1-point improvement in CEAP [clinical, etiology, anatomy, pathophysiology] score) at 2 weeks, 6 months, 12 months, and 24 months was 76%, 85%, 87%, and, 100%, respectively. Estimated primary patency at 6, 12, and 24 months was 91%, 88%, and 62%, respectively, with a mean estimated duration of patency of 51 months.

Several case series have strongly supported the value of iliac venous stenting, but the first—albeit small—randomized trial comparing iliac vein stenting with medical management was published in 2018.[11] Fifty-one limbs in 50 patients with CEAP class C3 to C6 disease, a visual analog score > 3, and VCSS of 10 were randomized to iliac vein stenting or compression and phlebotonic drugs. Primary, primary-assisted, and secondary patency were 92%, 96%, and 100% at 6 months, respectively, and remained stable out to 18 months. More importantly, at 6 months, patients randomized to stenting showed significantly greater improvements in pain score, VCSS, and QOL. Clinical improvement favored those randomized to stenting.

McDevitt et al performed the first study of iliocaval stent reconstruction for chronic iliocaval thrombosis in pediatric patients.[12] Fourteen patients < 21 years were analyzed, and stenting technical success, complications, clinical outcomes, and stent patency were recorded. Using a combination of blunt (n = 12; 86%) and sharp (n = 2; 14%) recanalization techniques, the authors achieved a 100% technical success rate with the Wallstent endoprosthesis (Boston Scientific Corporation) (n = 10; 71%), Wallstent and the Smart Control stent system (Cordis, a Cardinal Health company) (n = 1; 7.1%), Palmaz endoprosthesis (Cordis, a Cardinal Health company) (n = 1; 7.1%), Viabahn endoprosthesis (Gore & Associates) (n = 1; 7.1%), and Wallstent and the Gianturco Z-stent (Cook Medical) (n = 1; 7.1%). There were no moderate or severe adverse events. Clinical success (defined as a ≥ 1-point improvement in CEAP score) at 2 weeks, 6 months, and 12 months was 85%, 82%, and 83%, respectively. Estimated primary patency at 6 and 12 months was 86% and 64%, respectively. The mean estimated duration of primary patency was 436 days.

As previously demonstrated, most chronic venous occlusions may be crossed and treated with blunt recanalization; however, sharp recanalization is an alternative recanalization method for patients who have

failed traditional techniques. Another study conducted by McDevitt et al assessed the technical success and complications of 123 patients who underwent sharp recanalization of chronic venous occlusions.[13] Sharp recanalization was performed by directing a needle toward a targeting device (loop snare or partially deployed Wallstent). The authors reported a technical success rate of 90.2%, and there was no significant difference in the technical success rate when stratified by site of occlusion. There were three (2.4%) severe adverse events.

Why These Studies Are Important

These series demonstrate that endovascular venous stent reconstruction is technically feasible with good clinical outcomes and durable patency rates in many clinical scenarios. For instance, pediatric patients have differing risk factors for iliocaval thrombosis than adults, including congenital iliocaval anomalies or prothrombotic hematologic disorders. Despite these differences, successful stent reconstruction with acceptable patency rates may be achieved in this unique population.

Importantly, a structured postprocedural anticoagulation regimen is critical to maintaining stent patency after endovascular venous reconstruction. The general anticoagulation algorithm for the aforementioned studies included immediate 1 mg/kg enoxaparin twice daily followed by transition to warfarin or novel oral anticoagulant 4 weeks after the procedure to be continued for at least 1 year and antiplatelet therapy consisting of 75 mg/day clopidogrel and 81 mg aspirin daily.[12,13] Clopidogrel was discontinued 2 months after the procedure, and aspirin was prescribed indefinitely if there was no contraindication. However, the optimal anticoagulation and antiplatelet regimens remain undefined.

APPROVAL AND ADOPTION OF DEDICATED VENOUS STENTS

Along with the increased adoption of endovascular stent reconstruction, 2019 also included the FDA approval of two dedicated venous stents. The Venovo venous stent (BD Interventional) is a nitinol self-expanding stent with 3-mm flared ends to assist with wall apposition that has had success in treating patients with iliofemoral thrombosis. The Venovo venous stent is available in a wide spectrum of diameters (10–20 mm) and lengths (40–160 mm), providing increased utility when treating venous occlusive disease. The deployment mechanism of the Venovo stent allows for more precise delivery and does not foreshorten when deployed, as compared to the Wallstent.

A multicenter study of 170 patients who underwent placement of the Venovo stent demonstrated a primary patency rate of 88% at 12 months, without evidence of stent fracture.[14] Additionally, there was a statistically significant VCSS improvement at 12 months. Similar results were found in a separate analysis of 116 Venovo stent placements, demonstrating 98% and 97% primary patency rates at 1 and 6 months, respectively.[15] Early stent reocclusion (within 3 days) was documented in three (4%) patients. There were significant improvements in the revised VCSS and moderate improvement in CEAP scores at both follow-up intervals.

The Vici venous stent (Boston Scientific Corporation) is another dedicated self-expanding nitinol venous stent with a closed-cell design. The stent has increased radial strength, which minimizes crushing deformities when treating chronic venous occlusions, particularly in patients with May-Thurner syndrome. Like Venovo, the Vici stent is also available in a variety of diameters (12–16 mm) and lengths (60–120 mm).

An initial study of the Vici stent in 30 patients with iliofemoral venous obstruction achieved a 100% technical success rate, with no residual stenosis, and a 93% primary patency rate at 12 months.[16] The authors found significant improvements in QOL at 6 and 12 months as demonstrated by improved VCSS and Chronic Venous Insufficiency Questionnaire score. A larger analysis of 88 patients who underwent placement of the Vici stent demonstrated primary, primary-assisted, and secondary patency rates of 59%, 78%, and 87% at 1 year, respectively, and 51%, 73%, and 82% at 2 years, respectively.[17] Stent fracture occurred in three (3%) patients, all at the inguinal ligament. Villalta scores at 6, 12, and 24 months were all significantly lower than at baseline. Clinically significant improvement was observed in 66% of patients at 6 months, in 72% at 12 months, and in 70% at 24 months. Of the limbs with prestent ulceration, 80% had healed at 24 months.

Why These Studies Are Important

The results of these studies indicate that the newly approved venous stents are safe to place and have patency rates comparable to studies performed exclusively in patients treated with arterial stents. Because venous occlusive disease is generally found in larger-diameter vessels that are subject to external compression at vessel crossings, the venous stents have been designed to provide high radial strength while allowing sufficient flexibility. The recent data regarding venous stents demonstrate that the Venovo and Vici stents result in similar efficacy compared to arterial stents placed in the venous

system. Importantly, the location and etiology of the treated lesions affect the expected patency rates and should be compared accordingly. Postthrombotic occlusions (PTOs) have worse patency rates than nonthrombotic iliac vein lesions (NIVLs). The cumulative primary stent patency rate at 12 months for the Vici stent was 100% in patients with NIVLs and 87% in patients with PTOs. For comparison, the cumulative primary patency rates in the same groups in the Neglén et al study using only Wallstents were 93% and 85% at 12 months, respectively.[18]

NEXT-GENERATION THROMBECTOMY DEVICES

Pulmonary embolism (PE) and acute DVT are associated with substantial morbidity and mortality. Interventions targeted at treating patients with intermediate-risk PE and acute DVT—including systemic thrombolysis and catheter-directed thrombolysis (CDT)—have been associated with an increased risk of major bleeding; additionally, many patients have contraindications to thrombolysis. Next-generation percutaneous mechanical thrombectomy devices, including FlowTriever (Inari Medical), ClotTriever (Inari Medical), Indigo (Penumbra, Inc.), and Jeti (Walk Vascular, LLC), have demonstrated favorable safety profiles and may be less invasive than other rheolytic thrombectomy devices.

The FlowTriever retrieval and aspiration system is a single-use mechanical thrombectomy device that received FDA approval in 2018 for the treatment of PE. It consists of a compliant, large-bore, 20-F aspiration guide catheter that tracks over a 0.035-inch guidewire and a catheter system of self-expanding nitinol discs that mechanically disrupt thrombi. The FLARE study consisted of 106 patients with symptomatic PE and a right ventricular (RV)/left ventricular (LV) ratio ≥ 0.9, and it assessed safety outcomes and average RV/LV ratio reductions.[19] After thrombectomy, the average RV/LV ratio was 0.38 at 48 hours postprocedure ($P < .0001$), equating to an approximate 25.1% decrease. Average postprocedural mean pulmonary artery pressure (mPAP) significantly decreased from baseline (27.8 vs 29.8 mm Hg, respectively; $P = .001$), and this was more pronounced in patients who presented with pulmonary hypertension. Four patients (3.8%) experienced six MAEs, which were all procedure related and not device related: all four patients experienced clinical deterioration, with one major bleeding event and one pulmonary vascular injury. There were 10 additional serious adverse events within 30 days of the index procedure. In a subsequent study conducted by Wible et al, within a cohort of 46 patients who underwent PE treatment with the FlowTriever device, the average mPAP showed significant improvement from preprocedural levels (27 vs 33.9 mm Hg, respectively; $P < .0001$).[20] Only two (4.6%) MAEs occurred, including hemoptysis and procedure-related blood loss—both requiring transfusions. There were no delayed procedure-related complications.

Similar to the FLARE study, the EXTRACT-PE trial demonstrated the safety and efficacy of the Indigo aspiration system for treating acute PE.[21] In this study, which met its primary endpoints in 2019 and included 119 patients, there was a significant mean reduction of 27.3% in the RV/LV ratio at 48 hours after the intervention. Median aspiration system usage was 37 minutes, with a median intensive care unit stay of 1 day. The MAE rate was 1.7% at 48 hours.

Shifting to the treatment of DVT, the ClotTriever thrombectomy system is a sheath- and catheter-based system consisting of a nitinol-coring element and a braided collection bag device. It has received FDA approval for endovascular treatment of soft thrombi and emboli. The ClotTriever system offers benefits over pharmacomechanical-based and large-bore mechanical thrombectomy systems in treating venous thrombosis. It eliminates the need for thrombolytics and venovenous bypass, uses a single access site, and requires smaller access sheaths (13 F). The ClotTriever has been used to successfully treat free-floating IVC tumor thrombus without complications.[22] Enrollment for the CLOUT trial (NCT03575364) is currently underway.

In addition to the ClotTriever thrombectomy system, 2019 marked the introduction of the Jeti system for the treatment of DVT. The thrombectomy device—which features a high-pulse saline jet inside an inner catheter—allows for single-session thrombectomy, with minimal catheter occlusion, decreased exposure to systemic

FUTURE NEEDS IN VENOUS DISEASE

- A properly constructed instrument for measuring PTS and evaluating the impact of new therapies in preventing PTS
- Defined optimal anticoagulation and antiplatelet regimens to follow endovascular venous reconstruction
- Published results from thrombectomy device trials, including EXTRACT-PE and CLOUT
- Further studies on appropriate clinical applications of reflux therapies to avoid overuse
- More efficacious thrombectomy devices for chronic venous thrombosis
- AI and machine learning techniques for venous disease treatment

hemolytic compounds due to the location of the saline jet adjacent to the aspiration mechanism, and limited need for extended catheter-based thrombolysis. An audible alert feature that is activated during aspiration also limits blood loss during thrombectomy procedures.

Why These Devices Are Important

Although no intervention is entirely exempt from procedure-related complications, the newer-generation thrombectomy devices have strikingly low rates of major bleeding events and no documented occurrences of intracerebral hemorrhage, which is a dreaded complication associated with CDT. By using decreased thrombolytic doses or avoiding thrombolytics altogether, the newer-generation thrombectomy devices exhibit excellent safety profiles, with similar rates of clinical deterioration compared with anticoagulation alone for treating PE and DVT.

OPTIMIZATION OF SUPERFICIAL VENOUS REFLUX THERAPIES

Significant efforts have been recently dedicated toward studying the impact of superficial venous reflux therapies. The EVRA trial provided strong evidence that early endovenous ablation of superficial venous reflux results in faster healing of venous leg ulcers.[23] Given these findings, increased attention has been directed toward determining the appropriate clinical applications of reflux therapies to avoid overuse. In particular, nonthermal nontumescent (NTNT) therapies have gained increased attention because these methods avoid the need for perivenous tumescent anesthesia, decrease the number of needle sticks, and avoid the risk of thermal nerve damage associated with radiofrequency ablation (RFA).

Two recent studies compared the short- and long-term outcomes of cyanoacrylate closure (CAC) versus RFA for treatment of incompetent great saphenous veins (GSVs). Ovalı and Sevin conducted a retrospective analysis of 244 patients who underwent GSV ablation (128 patients in the RFA group, 116 patients in the CAC group). The analysis compared recanalization-free survival rates at 1, 3, 6, and 12 months, as well as complication rates.[24] Total occlusion of the GSV was evaluated on color Doppler ultrasound immediately after all procedures. The mean procedure duration for the RFA and CAC groups was 45 and 20 minutes, respectively. At 12 months postprocedure, 99.5% of patients in the CAC group demonstrated complete occlusion, compared with 96.6% in the RFA group (P = .072). One major complication (skin burn) occurred in the RFA group. There were significantly more side effects in the RFA group (n = 85) than the CAC group (n = 38), primarily consisting of severe pain, ecchymosis, and sensitivity. Gibson et al randomized 222 patients to CAC using the VenaSeal closure system (Medtronic) or RFA.[25] At 24 months, GSV closure rates were 95.3% and 94% in the CAC and RFA groups, respectively (P = .0034). By 24 months, both the venous disease–specific QOL and overall QOL had improved, with no significant difference between the two groups.

Why These Therapies Are Important

NTNT therapies, specifically CAC, appear to provide a durable and safe treatment modality for chronic venous insufficiency that is comparable to RFA. Another NTNT therapy is mechanochemical endovenous ablation, which uses mechanical endothelial damage and a rotating wire combined with liquid sclerosant to provide satisfactory long-term occlusion rates.[26] Avoiding the need for perivenous tumescent anesthesia and removing the risk of thermal nerve damage may reduce cost and increase patient comfort, and these factors should be discussed with patients when selecting a treatment option for venous insufficiency. Finally, compared to placebo, polidocanol endovenous microfoam (1%) has significantly improved patient symptoms and QOL.[27] Regardless, the extent of disease, presence of reflux, procedural costs, and patient expectations all contribute to the decision-making process regarding the treatment modality for chronic venous insufficiency.

FUTURE DIRECTIONS AND ARTIFICIAL INTELLIGENCE IN VENOUS DISEASE

There have been many practice-changing breakthroughs over the past year in the realm of venous disease: new thrombectomy devices that do not require thrombolysis, innovative venous recanalization and stent reconstruction techniques, and new insights into the patient populations that may benefit most from CDT. Although the future directions of venous disease treatments are unknown, it appears likely that artificial intelligence (AI) will play an increasingly important role in many clinical aspects of care. AI and machine learning techniques may be used to assist in patient selection by analyzing baseline clinical, laboratory, and imaging data to determine which patients will respond to CDT and venous stent reconstruction.[28] Additionally, deep learning algorithms might be used to identify imaging characteristics consistent with iliocaval occlusion and provide an automatic specialist referral if the patient meets the clinical criteria for endovascular intervention.[29] Projecting further, AI may assist with intraprocedural guidance by incorporating image fusion via registration algorithms,

using superimposed preoperative imaging and real-time intraprocedural fluoroscopy to assist with catheter navigation and stent sizing. An additional avenue for further innovation for general venous disease management is the introduction of more efficacious thrombectomy devices for chronic venous thrombosis. Although not all of these technologies may come to fruition, AI appears to have the potential to improve physician workflow, while granting additional substantial opportunities for patient-centered venous care. ■

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