Clinical UM Guideline

Subject:	Venous Angioplasty with or without Stent Placement or Venous Stenting Alone		
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Description

This document addresses venous angioplasty with or without stent placement, or venous stenting alone, as a treatment modality for a variety of conditions, including, but not limited to: venous thoracic outlet syndrome, superior vena cava syndrome, Budd-Chiari syndrome, congenital cardiac defects, lower extremity venous congestion, and as a method to improve venous flow in individuals with multiple sclerosis and chronic cerebrospinal venous insufficiency (CCSVI).

Note: Angiographic evaluation and endovascular intervention for dialysis access circuit dysfunction is not addressed in this document. For more information, please refer to:

- CG-SURG-93 Angiographic Evaluation and Endovascular Intervention for Dialysis Access Circuit Dysfunction
- CG-SURG-76 Carotid, Vertebral and Intracranial Artery Stent Placement with or without Angioplasty

Clinical Indications

Medically Necessary:

Venous angioplasty with or without stent placement or venous stenting alone is considered **medically necessary** for treatment of the following conditions:

A. Venous thoracic outlet syndrome; **or**
B. Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome); **or**
C. Superior vena cava syndrome; **or**
D. Iliac vein compression syndrome (for example, May-Thurner Syndrome); **or**
E. Pulmonary vein stenosis; **or**
F. Congenital heart disease including, but not limited to:
   1. Stenosis or hypoplasia of a pulmonary artery in a child; **or**
   2. Symptomatic stenosis/occlusion of superior or inferior vena cava; **or**
   3. Venous narrowing due to repair of sinus venosus atrial septal defect (ASD); **or**
   4. Venous obstruction of an atrial baffle following Mustard or Senning repair of transposition of the great arteries;

or

G. Idiopathic intracranial hypertension (IIH), also known as pseudotumor cerebri, when the following criteria are met:
   1. Documented IIH diagnosis; **and**
   2. *Either* of the following:
      a. Presence of bilateral venous sinus stenosis, **or**
      b. Unilateral stenosis and contralateral hypoplasia;

   and
   3. Individual has refractory disease or is intolerant to maximum medical therapy.

Not Medically Necessary:

Venous angioplasty with or without stent placement or venous stenting alone is considered **not medically necessary** for the treatment of all other conditions not listed above including, but not limited to:

A. Multiple sclerosis; **or**
B. Chronically occluded iliac veins; **or**
C. Ilio-femoral venous thrombosis; **or**
D. Nutcracker syndrome.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Medically Necessary:

CPT	
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein

37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein

ICD-10 Procedure

027Q04Z-027Q4ZZ	Dilation of right pulmonary artery [by approach and with or without device; includes codes 027Q04Z, 027Q0DZ, 027Q0ZZ, 027Q34Z, 027Q3DZ, 027Q3ZZ, 027Q44Z, 027Q4DZ, 027Q4ZZ]
027R04Z-027R4ZZ	Dilation of left pulmonary artery [by approach and with or without device; includes codes 027R04Z, 027R0DZ, 027R0ZZ, 027R34Z, 027R3DZ, 027R3ZZ, 027R44Z, 027R4DZ, 027R4ZZ]
027S04Z-027S4ZZ	Dilation of right pulmonary vein [by approach and with or without device; includes codes 027S04Z, 027S0DZ, 027S0ZZ, 027S34Z, 027S3DZ, 027S3ZZ, 027S44Z, 027S4DZ, 027S4ZZ]
027T04Z-027T4ZZ	Dilation of left pulmonary vein [by approach and with or without device; includes codes 027T04Z , 027T0DZ, 027T0ZZ, 027T34Z, 027T3DZ, 027T3ZZ, 027T44Z, 027T4DZ, 027T4ZZ]
027V04Z-027V4ZZ	Dilation of superior vena cava [by approach and with or without device; includes codes 027V04Z, 027V0DZ, 027V0ZZ, 027V34Z, 027V3DZ, 027V3ZZ, 027V44Z, 027V4DZ, 027V4ZZ]
05750D1-05764ZZ	Dilation of subclavian vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05750D1, 05750DZ, 05750Z1, 05750ZZ, 05753D1, 05753DZ, 05753Z1, 05753ZZ, 05754D1, 05754DZ, 05754Z1, 05754ZZ, 05760D1, 05760DZ, 05760Z1, 05760ZZ, 05763D1, 05763DZ, 05763Z1, 05763ZZ, 05764D1, 05764DZ, 05764Z1, 05764ZZ]
05790D1-057A4ZZ	Dilation of brachial vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05790D1, 05790DZ, 05790Z1, 05790ZZ, 05793D1, 05793DZ, 05793Z1, 05793ZZ, 05794D1, 05794DZ, 05794Z1, 05794ZZ, 057A0D1, 057A0DZ, 057A0Z1, 057A0ZZ, 057A3D1, 057A3DZ, 057A3Z1, 057A3ZZ, 057A4D1, 057A4DZ, 057A4Z1, 057A4ZZ]
057B0D1-057C4ZZ	Dilation of basilic vein [right or left, by approach and with or without device or drug-coated balloon, includes 057B0D1, 057B0DZ, 057B0Z1, 057B0ZZ, 057B3D1, 057B3DZ, 057B3Z1, 057B3ZZ, 057B4D1, 057B4DZ, 057B4Z1, 057B4ZZ, 057C0D1, 057C0DZ, 057C0Z1, 057C0ZZ, 057C3D1, 057C3DZ, 057C3Z1, 057C3ZZ, 057C4D1, 057C4DZ, 057C4Z1, 057C4ZZ]
057D0D1-057F4ZZ	Dilation of cephalic vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 057D0D1, 057D0DZ, 057D0Z1, 057D0ZZ, 057D3D1, 057D3DZ, 057D3Z1, 057D3ZZ, 057D4D1, 057D4DZ, 057D4Z1, 057D4ZZ, 057F0D1, 057F0DZ, 057F0Z1, 057F0ZZ, 057F3D1, 057F3DZ, 057F3Z1, 057F3ZZ, 057F4D1, 057F4DZ, 057F4Z1, 057F4ZZ]

057G0DZ-057H4ZZ	Dilation of hand vein [right or left, by approach and with or without device, includes codes 057G0DZ, 057G0ZZ, 057G3DZ, 057G3ZZ, 057G4DZ, 057G4ZZ, 057H0DZ, 057H0ZZ, 057H3DZ, 057H3ZZ, 057H4DZ, 057H4ZZ]
06700DZ-06704ZZ	Dilation of inferior vena cava [by approach and with or without device; includes codes 06700DZ, 06700ZZ, 06703DZ, 06703ZZ, 06704DZ, 06704ZZ]
06740DZ-06744ZZ	Dilation of hepatic vein [by approach and with or without device; includes codes 06740DZ, 06740ZZ, 06743DZ, 06743ZZ, 06744DZ, 06744ZZ]
06780DZ-06784ZZ	Dilation of portal vein [by approach and with or without device; includes codes 06780DZ, 06780ZZ, 06783DZ, 06783ZZ, 06784DZ, 06784ZZ]
067D0DZ-067D4ZZ	Dilation of left common iliac vein [by approach and with or without device; includes codes 067D0DZ, 067D0ZZ, 067D3DZ, 067D3ZZ, 067D4DZ, 067D4ZZ]

ICD-10 Diagnosis

C38.1-C38.3	Malignant neoplasm of mediastinum
C38.8	Malignant neoplasm of overlapping sites of heart, mediastinum and pleura
G54.0	Brachial plexus disorders
I26.01-I26.99	Pulmonary embolism
I82.0	Budd-Chiari syndrome
I82.210-I82.211	Embolism and thrombosis of superior vena cava
I82.220-I82.221	Embolism and thrombosis of inferior vena cava
Q20.0-Q20.9	Congenital malformations of cardiac chambers and connections
Q21.0-Q21.9	Congenital malformations of cardiac septa
Q25.0-Q25.9	Congenital malformations of great arteries
Q26.0-Q26.9	Congenital malformations of great veins
R10.84	Generalized abdominal pain
R16.0	Hepatomegaly, not elsewhere classified
R18.8	Other ascites

When services may be Medically Necessary when criteria are met:
For the procedure codes listed above for the following diagnoses

ICD-10 Diagnosis

I28.8	Other diseases of pulmonary vessels [specified as pulmonary vein stenosis]
I87.1	Compression of vein [specified as superior vena cava syndrome or iliac vein compression]

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met and for all other diagnoses not listed.

When services are also Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

ICD-10 Procedure	
05700DZ-05704ZZ	Dilation of azygos vein [by approach and with or without device; includes codes 05700DZ, 05700ZZ, 05703DZ, 05703ZZ, 05704DZ, 05704ZZ]
05710DZ-05714ZZ	Dilation of hemiazygos vein [by approach and with or without device, includes codes 05710DZ, 05710ZZ, 05713DZ, 05713ZZ, 05714DZ, 05714ZZ]
05730D1-05744ZZ	Dilation of innominate vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05730D1, 05730DZ, 05730Z1, 05730ZZ, 05733D1, 05733DZ, 05733Z1, 05733ZZ, 05734D1, 05734DZ, 05734Z1, 05734ZZ, 05740D1, 05740DZ, 05740Z1, 05740ZZ, 05743D1, 05743DZ, 05743Z1, 05743ZZ, 05744D1, 05744DZ, 05744Z1, 05744ZZ]
05770D1-05784ZZ	Dilation of axillary vein [right or left, by approach and with or without device or drug-coated balloon, includes codes 05770D1, 05770DZ, 05770Z1, 05770ZZ, 05773D1, 05773DZ, 05773Z1, 05773ZZ, 05774D1, 05774DZ, 05774Z1, 05774ZZ, 05780D1, 05780DZ, 05780Z1, 05780ZZ, 05783D1, 05783DZ, 05783Z1, 05783ZZ, 05784D1, 05784DZ, 05784Z1, 05784ZZ]
057M0DZ-057N4ZZ	Dilation of internal jugular vein [right or left, by approach and with or without device; includes codes 057M0DZ, 057M0ZZ, 057M3DZ, 057M3ZZ, 057M4DZ, 057M4ZZ, 057N0DZ, 057N0ZZ, 057N3DZ, 057N3ZZ, 057N4DZ, 057N4ZZ]
057P0DZ-057Q4ZZ	Dilation of external jugular vein [right or left, by approach and with or without device; includes codes 057P0DZ, 057P0ZZ, 057P3DZ, 057P3ZZ, 057P4DZ, 057P4ZZ, 057Q0DZ, 057Q0ZZ, 057Q3DZ, 057Q3ZZ, 057Q4DZ, 057Q4ZZ]
057R0DZ-057S4ZZ	Dilation of vertebral vein [right or left, by approach and with or without device; includes codes 057R0DZ, 057R0ZZ, 057R3DZ, 057R3ZZ, 057R4DZ, 057R4ZZ, 057S0DZ, 057S0ZZ, 057S3DZ, 057S3ZZ, 057S4DZ, 057S4ZZ]
057T0DZ-057V4ZZ	Dilation of face vein [right or left, by approach and with or without device; includes codes 057T0DZ, 057T0ZZ, 057T3DZ, 057T3ZZ, 057T4DZ, 057T4ZZ, 057V0DZ, 057V0ZZ, 057V3DZ, 057V3ZZ, 057V4DZ, 057V4ZZ]
057Y0DZ-057Y4ZZ	Dilation of upper vein [by approach and with or without device; includes codes 057Y0DZ, 057Y0ZZ, 057Y3DZ, 057Y3ZZ, 057Y4DZ, 057Y4ZZ]
06710DZ-06714ZZ	Dilation of splenic vein [by approach and with or without device; includes codes 06710DZ, 06710ZZ, 06713DZ, 06713ZZ, 06714DZ, 06714ZZ]
06720DZ-06724ZZ	Dilation of gastric vein [by approach and with or without device; includes codes 06720DZ, 06720ZZ, 06723DZ, 06723ZZ, 06724DZ, 06724ZZ]
06730DZ-06734ZZ	Dilation of esophageal vein [by approach and with or without device; includes codes 06730DZ, 06730ZZ, 06733DZ, 06733ZZ, 06734DZ, 06734ZZ]
06750DZ-06754ZZ	Dilation of superior mesenteric vein [by approach and with or without device; includes codes 06750DZ, 06750ZZ, 06753DZ, 06753ZZ, 06754DZ, 06754ZZ]
06760DZ-06764ZZ	Dilation of inferior mesenteric vein [by approach and with or without device; includes codes 06760DZ, 06760ZZ, 06763DZ, 06763ZZ, 06764DZ, 06764ZZ]
06770DZ-06774ZZ	Dilation of colic vein [by approach and with or without device; includes codes 06770DZ, 06770ZZ, 06773DZ, 06773ZZ, 06774DZ, 06774ZZ]

06790DZ-067B4ZZ	Dilation of renal vein [right or left, by approach and with or without device; includes codes 06790DZ, 06790ZZ, 06793DZ, 06793ZZ, 06794DZ, 06794ZZ, 067B0DZ, 067B0ZZ, 067B3DZ, 067B3ZZ, 067B4DZ, 067B4ZZ]
067C0DZ-067C4ZZ	Dilation of right common iliac vein [by approach and with or without device; includes codes 067C0DZ, 067C0ZZ, 067C3DZ, 067C3ZZ, 067C4DZ, 067C4ZZ]
067F0DZ-067G4ZZ	Dilation of external iliac vein [right or left, by approach and with or without device; includes codes 067F0DZ, 067F0ZZ, 067F3DZ, 067F3ZZ, 067F4DZ, 067F4ZZ, 067G0DZ, 067G0ZZ, 067G3DZ, 067G3ZZ, 067G4DZ, 067G4ZZ]
067H0DZ-067J4ZZ	Dilation of hypogastric vein [right or left, by approach and with or without device; includes codes 067H0DZ, 067H0ZZ, 067H3DZ, 067H3ZZ, ,067H4DZ, 067H4ZZ, 067J0DZ, 067J0ZZ, 067J3DZ, ,067J3ZZ, 067J4DZ, 067J4ZZ]
067M0DZ-067N4ZZ	Dilation of femoral vein [right or left, by approach and with or without device; includes codes 067M0DZ, 067M0ZZ, 067M3DZ, 067M3ZZ, 067M4DZ, 067M4ZZ, 067N0DZ, 067N0ZZ, 067N3DZ, 067N3ZZ, 067N4DZ, 067N4ZZ]
067P0DZ-067Q4ZZ	Dilation of saphenous vein [right or left, by approach and with or without device; includes codes 067P0DZ, 067P0ZZ, 067P3DZ, 067P3ZZ, 067P4DZ, 067P4ZZ, 067Q0DZ, 067Q0ZZ, 067Q3DZ, 067Q3ZZ, 067Q4DZ, 067Q4ZZ]
067T0DZ-067V4ZZ	Dilation of foot vein [right or left, by approach and with or without device; includes codes 067T0DZ, 067T0ZZ, 067T3DZ, 067T3ZZ, 067T4DZ, 067T4ZZ, 067V0DZ, 067V0ZZ, 067V3DZ, 067V3ZZ, 067V4DZ, 067V4ZZ]
067Y0DZ-067Y4ZZ	Dilation of lower vein [by approach and with or without device; includes codes 067Y0DZ, 067Y0ZZ, 067Y3DZ, 067Y3ZZ, 067Y4DZ, 067Y4ZZ]

ICD-10 Diagnosis

All diagnoses

Intracranial venous sinus

When services may be Medically Necessary when criteria are met:

For the following procedure and diagnosis codes when described as intracranial venous sinus stenting

CPT

61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous
61635	Transcatheter placement of an intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed

ICD-10 Procedure

057L0DZ-057L4ZZ	Dilation of intracranial vein [by approach & with or without device, includes codes 057L0DZ, 057L0ZZ, 057L3DZ, 057L3ZZ, 057L4DZ, 057L4ZZ]

ICD-10 Diagnosis

G93.2	Benign intracranial hypertension

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met and for venous angioplasty or stenting for all other indications

Discussion/General Information

Venous angioplasty is a procedure which can be performed during a venogram to open or bypass veins. It can also be used for placement of a stent, which keeps the vessel in an open position to allow for improved blood flow.

There are numerous conditions which have been successfully treated with venous angioplasty, including Budd-Chiari syndrome, superior vena cava syndrome, iliac vein compression syndrome (for example, May-Thurner syndrome), idiopathic intracranial hypertension, and congenital heart disease. Venous angioplasty has been studied to treat a variety of other conditions, including but not limited to the treatment of MS or CCSVI, chronically occluded iliac veins, iliofemoral venous thrombosis, and nutcracker syndrome; however, use is not in accordance with generally accepted standards of medical practice.

Venous Thoracic Outlet Syndrome (vTOS)

vTOS is caused by compression of peripheral nerves and vascular structures along their course through the upper thoracic aperture to the axilla (Skalicka, 2011). The evidence regarding venous angioplasty for vTOS consists mainly of retrospective analyses (Bamford, 2012; Skalicka, 2011).

Skalicka and colleagues (2011) performed a retrospective analysis of 73 individuals treated at a single institution between 2001 and 2007 for venous thrombotic complications secondary to vTOS. Long-term follow-up with duplex ultrasound was completed 6-12 months after the initial clinical event. The initial treatment provided was based on severity of symptoms. Endovascular procedures were attempted in 41 cases (56%) as a primary thrombosis treatment. A total of 12 additional individuals were treated with an endovascular approach due to failure of conservative treatment based on low molecular weight heparin alone. Endovascular treatment by balloon angioplasty was performed in 35 individuals. In 7 cases, re-treatment was necessary due to suboptimal patency or re-thrombosis. In 12 individuals, failure of the endovascular approach resulted in primary surgical intervention consisting of thrombectomy followed by decompression. An additional 22 individuals with persistent symptoms underwent subsequent surgical decompression. Conservative treatment consisting of intravenous (IV) or low molecular weight heparin was used for 32 cases (44%) with mild symptoms. Of these, 12 subsequently were referred for endovascular treatment and 8 for elective surgery due to persistent symptoms. None of the cases required primary surgical thrombectomy or revascularization. Follow-up assessment of patency by ultrasound and clinical exam was performed in 62 (82%). Surgery was associated with a significantly lower rate of ultrasound-detected signs of persistent vascular compression as compared to treatment consisting only of endovascular and/or conservative therapy. However, the rate of persistent clinical symptoms was similar in both groups. Study data demonstrated that initial endovascular treatment provided as first-line therapy to highly symptomatic individuals and to those with failure of conservative treatment improved symptoms in 77%, avoiding the need for acute surgery. A total of 13 (23%) did have persistent clinical symptoms. Study limitations included a limited sample of

cases from a single center. The authors concluded that long-term outcomes in those for whom surgery was required were satisfactory and comparable to those requiring only conservative and/or endoluminal treatment.

Bamford and colleagues (2012), in a single-center retrospective review, evaluated the management and outcomes of vTOS from 2002 through 2009. Initially, 35 cases were identified, of which all underwent first rib resection for subclavian venous thrombosis. Two individuals were excluded from the review due to loss of follow-up and incomplete notes. Of the 33 cases reviewed, 20 individuals were treated for vTOS prior to 2006 (group A) and the remaining 13 were treated in 2006 and after (group B). Duplex ultrasound imaging was recorded on presentation in 31 of the 33 cases (94%) and of these, 3 cases had additional magnetic resonance angiography (MRA) of the affected limb. A total of 17 of the 33 cases (51.5%) were initially treated with catheter-directed thrombolysis (CDT) and 6 cases (35%) underwent balloon angioplasty before decompression of the thoracic outlet. The remaining 11 (65%) had recanalized sufficiently to proceed with thoracic outlet decompression with CDT alone. Most cases of CDT, 10/17 (58.8%) occurred in group B. In group A, most cases, 13/33 (39.3%) were treated initially with a variable period of anticoagulation. All individuals who subsequently underwent thoracic outlet decompression had evidence of venous recanalization before surgery. Postoperatively, 91% of individuals had patent veins at discharge from follow-up and were free of symptoms at a median of 44 months. Those treated within 7 days of symptom onset with CDT and excision of first rib in less than 30 days had improved symptom-free rates. The authors reported that the lack of power in this study made it difficult to reach firm conclusions regarding the effectiveness of the proposed protocol for vTOS management. Further noted was that while not conclusive, this study suggests that a treatment algorithm of early referral, immediate CDT and surgical decompression may lead to improved vTOS outcomes.

Thrombotic Obstruction of Major Hepatic Veins (Budd-Chiari Syndrome)

Data to support angioplasty with or without stent placement for the treatment of Budd-Chiari syndrome consists of multiple retrospective studies or case series of varying size (Fisher, 1999; Han, 2013; Meng, 2011; Pelage, 2003; Qiao, 2005; Zhang, 2003).

Meng and colleagues (2011) evaluated endovascular treatment of Budd-Chiari syndrome (BCS) in 903 cases at a single Chinese center. The obstruction in the inferior vena cava (IVC) was carried out first, then obliteration or stenosis in the IVC was opened or dilated and a stent was placed. The procedure was reported to be successful in 821 out of 903 cases. Complications included acute renal failure (8 cases), hepatic coma (2 cases), and acute heart failure (43 cases). The authors concluded that endovascular treatment has become the treatment of choice for BCS because of its minimal trauma and fast recovery.

Han and colleagues (2013) evaluated the long-term outcomes of percutaneous recanalization and predictors of patency and survival in a retrospective case series of individuals with BCS at a single Chinese center. Between July 1999 and August 2010, 177 consecutive cases of primary BCS were treated with percutaneous recanalization and followed up until their last clinical evaluation or death. Percutaneous recanalization was reported as technically successful in 168 of the 177 cases (95%). A total of 51 of the 168 individuals (30%) were treated with percutaneous transluminal angioplasty (PTA) alone and 117 (70%) were treated with a combination of PTA and stent placement. Procedure-related complications occurred in 7 of the 168 individuals (4%). The cumulative 1-, 5- and 10-year

primary patency rates were 95%, 77% and 58%, respectively. Independent predictors of reocclusion included increased white blood cell count and use of PTA alone. The cumulative 1-, 5- and 10-year secondary patency rates were 97%, 90% and 86%, respectively. There were 22 deaths during a median follow-up of 30 months (range, 0.25-137 months). The cumulative 1-, 5- and 10-year survival rates were 96%, 83% and 73%, respectively. Independent predictors of survival included variceal bleeding, increased alkaline phosphatase and blood urea nitrogen levels, and reocclusion.

Stenosis or Occlusion associated with Superior Vena Cava Syndrome

Superior vena cava stenting for the treatment of malignant and nonmalignant superior vena cava obstruction is well established (Schindler, 1999; Uberoi, 2006). Venous angioplasty is often necessary prior to stenting to offer safe palliation of potentially fatal complications associated with mediastinal malignant disease and compares very favorably with standard therapies such as chemotherapy and radiotherapy. Superior vena cava syndrome can also be caused by benign occlusion from chronic indwelling catheters resulting in arm or facial swelling, difficulty breathing, or an inability to obtain vital venous access, among others.

Iliac Vein Compression Syndrome (also known as, May-Thurner Syndrome)

Some common causes of iliac vein compression syndrome (IVCS) are trauma, iatrogenic injury, congenital hypoplasia/aplasia of the IVC, and hypercoagulability, but the most common cause is malignant, juxtahepatic invasion or extraluminal compression of the IVC (Kuetting, 2018). Diagnosis of iliac vein compression syndrome is based on the individual's clinical history and diagnostic imaging such as Doppler ultrasound, computed tomography venography (CTV), magnetic resonance venography, venography, and digital subtraction venography (DSV) (Liu, 2018).

Liu and colleagues (2014) published a prospective cohort study with the aim to assess the prevalence of IVCS in individuals with chronic venous disease (CVD) of the left lower extremity, evaluate the sensitivity and specificity of CTV in the diagnosis of IVCS, and determine clinical utility of endovascular treatment of IVCS. The authors evaluated 324 individuals with CVD of the left lower extremity for IVCS. Diagnosis of IVCS was established through clinical history, duplex ultrasonography, ascending venography, and CTV with a prevalence of 14.8% (48/324). For individuals with an IVCS diagnosis, "the visualization of a >50% reduction in the luminal diameter of the vein, the formation of collateral circulation, and a pressure gradient of > 2 mm Hg across the stenosis while the patient was in a supine position" was used to confirm it (Liu, 2014). IVCS-diagnosed individuals were included in the study and placed into one of two groups: thrombotic IVCS (n=12) or nonthrombotic IVCS (n=36). Results after endovascular treatment showed a technical success rate of 95.8%, a 1-year primary patency rate of 93% with no significant difference between the two groups (p=0.156), and few minor complications. Other 1-year outcomes included significant declines in median pain levels for both groups ($p<0.05$), edema relief rates of 81.8% and 58.5% in the thrombotic and nonthrombotic groups, respectively, and a rate of 71.4% for cumulative recurrence-free ulcer healing. In regard to CTV in the diagnosis of IVCS, the authors found it had the highest sensitivity and specificity compared to other imaging modalities used in the study; however, the values were not reported. Study limitations include small sample size and nonrandomized design. Larger randomized controlled trials are needed to confirm these findings.

Mousa and colleagues (2016) evaluated venous duplex ultrasound (VDUS) as an imaging modality in diagnosing iliac vein stenosis after standard treatment of active chronic venous ulcers. This was completed through a systematic retrospective review of a consecutive series of 36 individuals with 54 chronic venous ulcers on 38 limbs. Iliac vein stenosis was defined as > 50% stenosis. The authors found that chronic venous ulcers associated with a reflux duration >2.5 seconds as measured by VDUS had significantly more iliac vein stenosis than those with a reflux duration <2.5 seconds ($p<0.001$). Individuals with stent placement had significantly less recurrence of chronic venous ulcers ($p=0.031$). This study had positive findings; however, there were limitations to the study, including small sample size and retrospective design.

Liu and colleagues (2018) reported on an observational study that evaluated CTV in the diagnosis and severity assessment of IVCS. Blinded radiologists reviewed the imaging data of a group of individuals with CVD of the lower extremity (n=120) and a control group of individuals without CVD (n=68). Imaging data consisted of CTV, color ultrasonography, and conventional venography. The authors defined IVCS as "iliac vein compression > 50% in CVD patients" (Liu, 2018). Results showed that CTV required less procedure time when compared to conventional venography or color ultrasonography ($p<0.001$). In individuals with IVCS and venous ulcer [Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification: C5, healed venous ulcer; C6, active venous ulcer], ulcer healing time was significantly shorter in individuals with stent placement than those without stent placement ($p<0.001$). The authors concluded that CTV is safe and accurate in the diagnosis and severity assessment of IVCS, and iliac stent placement in CEAP 5 or 6 decreases healing time for venous ulcers caused by IVCS. Study limitations include data being collected at a single center, which may impact selection bias, small sample size, and retrospective design.

Kuetting and colleagues (2018) published a retrospective analysis that evaluated technical and clinical outcomes of endovascular therapy as a treatment for symptomatic, malignant IVCS. From May 2000 to December 2015, 19 individuals were treated with stenting for malignant IVC obstruction. The treatment resulted in 100% technical success and 79% clinical success, which was measured by symptom improvement either temporally or indefinitely. The evaluators concluded that endovascular therapy is safe and effective for symptomatic, malignant IVCS; however, there are study limitations, including lack of statistical analysis, small sample size, and retrospective study design.

When the right iliac vein rests on top of the left iliac vein, causing pressure, the pressure on the left iliac vein can cause blood to flow abnormally, the result is May-Thurner syndrome. May-Thurner syndrome is also known as iliac vein compression syndrome, iliocaval compression syndrome, or Cockett syndrome. Approximately 2% to 5% of individuals with chronic deep venous insufficiency of the left leg may have May-Thurner. May-Thurner has been shown to increase the likelihood of developing deep vein thrombosis (DVT). Endovascular therapy, specifically catheter-directed thrombolysis followed by stent placement, is the current primary intervention for May-Thurner syndrome (Moudgill, 2009). Review of the current literature, primarily case studies, case series, and retrospective studies indicates that angioplasty has also been used with mixed results.

Peters and colleagues (2012) report 3 cases and Zander (2008) reports 1 case of successful intervention in May-Thurner compression with angioplasty. However, Patel (2000) reports that 10 women with symptomatic May-Thurner syndrome failed an initial course of angioplasty and subsequently progressed to urokinase and stenting.

One retrospective case review from a surgical registry included 15 May-Thurner cases in which venous angioplasty with stenting restored and maintained venous flow through the compressed area. Titus and colleagues (2011) described a series of iliofemoral venous angioplasty and stenting occurring over a 4-year period. Charts were retrospectively reviewed for individual demographics, the extent of venous system involvement, the time course of the venous pathology, and any underlying cause. The 15 (42%) individuals with a recognized underlying etiology had been diagnosed with May-Thurner syndrome. An etiology was not recognized in 9 cases. A total of 36 individuals (40 limbs) were stented from January 2005 through December 2008. Both lower extremities were involved in 4 individuals. Thrombolysis was performed in 19 cases (52.8%). The mean follow-up time period in the study population was 10.5 months. One stent in the study occluded acutely and required restenting. Primary patency rates at 6, 12 and 24 months were 88%, 78.3% and 78.3%, respectively. Secondary patency rates for the same time frames were 100%, 95% and 95%. Better outcomes were seen in stenting for May-Thurner syndrome and idiopathic causes, whereas external compression and thrombophilia seemed to portend less favorable outcomes ($p<0.001$). Symptomatic improvement was reported in 24 of 29 individuals (83%) contacted by telephone follow-up.

Hager and colleagues (2013) reported on a retrospective review of outcomes of endovascular intervention in May-Thurner syndrome individuals at two institutions. Based on presentation, individuals (n=70) were divided into either the postthrombotic group (group 1; 56 extremities) or the de novo presentation of chronic swelling/pain or ulceration but no deep vein thrombosis (DVT) group (group 2; 21 extremities). Endovascular intervention was performed on all individuals in both groups due to a > 50% diameter stenosis by IVUS or venogram. Mean follow up was 29.7 months in group 1 and 22.4 months in group 2. The authors found that "the overall primary patency of group 1 at 36 months by life-table analysis was 91% with a secondary patency of 95%, [and] the primary and secondary patency for group 2 was 91% at 36 months" (Hager, 2013). The retrospective design limits the study through possible reporting and selection bias, and missing data due to individuals lost to follow-up.

In 2021, the American Vein and Lymphatic Society (AVLS) convened an international, multidisciplinary panel charged with the development of a discriminative classification instrument for pelvic venous disorder (PeVD) to address May-Thurner, pelvic congestion, and nutcracker syndrome (Meissner, 2021). This instrument, the *Symptoms-Varices-Pathophysiology (SVP) classification for PeVD*, includes three domains: symptoms (S), varices (V), and pathophysiology (P), with the pathophysiology domain encompassing the anatomic (A), hemodynamic (H), and etiologic (E) features of the individual's disease. For those with pelvic origin lower extremity signs or symptoms, the SVP instrument is complementary to and should be used in conjunction with the Clinical-Etiologic-Anatomic-Physiologic (CEAP) classification. The SVP instrument accurately defines the diverse populations with PeVD.

Pulmonary Vein Stenosis

Expert specialty consensus review indicates that venous angioplasty may be used for the treatment of pulmonary vein stenosis. Recently there have been published reports of venous angioplasty being successfully used to treat pulmonary vein stenosis following lung transplant (Loyalka, 2012).

Congenital Heart Disease

Angioplasty has long played a role in the treatment of numerous congenital cardiac defects including stenosis or hypoplasia of a pulmonary artery; coarctation of the aorta, transposition of the great arteries, repair of sinus venosus atrial septal defect (ASD); or venous obstruction following Mustard or Senning repair of transposition of the great arteries (Allen, 1998).

Treatment of Multiple Sclerosis: Chronic Cerebrospinal Venous Insufficiency and Dysautonomia

Various reports in the peer reviewed published literature (Zamboni 2009a; Zamboni, 2009b) describe a potential relationship between the abnormal venous circulation termed chronic cerebrospinal venous insufficiency (CCSVI) and multiple sclerosis (MS).

The role of venous angioplasty as a potential treatment option for those with MS and CCSVI has been evaluated. Zamboni and colleagues (2009c) evaluated the influence of venous angioplasty on the clinical outcome of CCSVI and MS. The authors characterized CCSVI as multiple stenoses of the principal pathways of extracranial venous drainage, including the internal jugular veins (IJV) and the azygous (AZY) vein with development of insufficient drainage evidenced by cerebral magnetic resonance (MR) perfusion studies. In this study, a total of 65 consecutive participants with CCSVI and MS (35 with relapsing remitting MS [RRMS], 20 with secondary progressive MS [SPMS], and 10 with primary progressive MS [PPMS]), underwent venous angioplasty. Mean follow-up time was 18 months. Reported study results included lower postoperative venous pressure in the IJVs and AZY, a higher risk of restenosis in the IJVs compared with the AZY, improved MS clinical outcomes, and improved mental quality of life outcomes in all types of MS, except SPMS.

Doepp and colleagues (2010) evaluated CCSVI by performing extended extracranial and transcranial color-coded sonography studies on 56 participants with MS and 20 controls. Study results demonstrated that blood flow direction in the internal jugular veins (IJVs) and vertebral veins was normal (in all but 1 person) and IJV stenosis was not present in any participants. The authors concluded that the results of their study did not suggest restricted venous drainage in participants with MS and challenged the hypothesis that CCSVI plays a role in the pathogenesis of MS.

Sundstrom and colleagues (2010) tested the hypothesis of CCSVI on 21 individuals with RRMS and 20 controls. All study participants were examined with magnetic resonance imaging (MRI) and those with RRMS also received contrast enhanced MRA. Findings reported to be associated with the MS hypothesis of CCSVI were not able to be reproduced. The authors concluded they found no support for a treatment rationale of endovascular procedures like angioplasty or stenting for the treatment of individuals with CCSVI and MS.

Zivadinov and colleagues (2011) performed transcranial and extracranial Doppler imaging on 499 people to determine the prevalence of CCSVI in a larger, controlled and blinded study. The participants included 289 people with MS, 163 healthy controls (HC), 26 with other neurological diseases (OND), and 21 with clinically isolated syndrome (CIS) (having a first neurological episode that can often lead to definite MS). Researchers found an increased prevalence of CCSVI in MS, although lower than in earlier reports. In addition, CCSVI was found in non-MS participants. Variable rates were reported depending on whether or not borderline cases were included. When borderline cases were considered not to have CCSVI, the prevalence was 56.1% in MS, 42.3% in OND, 38.1% in CIS and 22.7% in HC. When borderline cases were excluded from calculations, the prevalence of CCSVI was 62.5% in MS, 45.8% in OND, 42.1% in CIS and 25.5% in HC. The researchers reported modest sensitivity and specificity and stated that their findings point against CCSVI as having a primary causative role in MS.

Kostecki and colleagues (2011) prospectively evaluated 6-month follow-up results of endovascular treatment of CCSVI and MS. A total of 36 participants with confirmed MS and CCSVI underwent endovascular treatment by means of a uni- or bilateral jugular vein angioplasty with optional stent placement. Their MS-related disability status and quality of life were evaluated at 1, 3 and 6 months postoperatively by the following scales: Expanded Disability Status Scale (EDSS), Multiple Sclerosis Impact Scale (MSIS-29), Epworth Sleepiness Scale (ESS), Heat Intolerance scale (HIS) and Fatigue Severity Scale (FSS). For patency and restenosis rate assessment, the control ultrasound (US) duplex Doppler examination was used. After the procedure at 6 months, restenosis in post-PTA jugular veins was found in 33% of cases. Among 17 individuals who underwent stent implantation into the jugular vein, restenosis or partial in-stent thrombosis was identified in 55% of the cases. At the 6-month follow-up, there was no significant improvement in the EDSS or the ESS. The endovascular treatment of the CCSVI improved the quality of life according to the MSIS-29 scale but only up to 3 months after the procedure (with no differences in the 6-month follow-up assessment). After the jugular vein angioplasty (with or without stent placement) at 6 months, a statistically significant improvement was observed only in the FSS and the HIS. Based on their findings, the researchers concluded that "endovascular treatment in individuals with MS and concomitant CCSVI did not have an influence on the patient's neurological condition; however, in the mid-term follow-up, an improvement concerning some parameters influencing the patient's quality-of-life parameters was observed." They also emphasized that there is the need for a well-designed randomized controlled trial.

Zamboni and colleagues (2012) reported on a small series of 8 individuals with ultrasound criteria for CCSVI undergoing immediate venoplasty compared to 7 individuals undergoing delayed venoplasty. There were improvements on the EDSS (expanded disability status scale) for both groups following treatment, but no difference between groups in the first 6 months comparing immediate- versus delayed-treatment subjects. The relapse rate during the initial 6 months was 0.12% in the treatment group versus 0.66% in the control group; however, this difference did not meet statistical significance. There were also trends toward improvement for the immediate-treatment group on MRI scans, such as the number of T2 lesions, but these differences also did not reach statistical significance. No short-term adverse events were reported following the procedure, but the rate of restenosis at 1 year was 27% in treated individuals.

Van Zuuren and colleagues (2012), in a Cochrane Review, concluded there was no high-level evidence to either support or refute the efficacy and safety of angioplasty for CCSVI in people with MS. The authors further noted that additional robust and well-designed studies are needed.

Siddiqui and colleagues (2014) performed a 2-phase study of venous angioplasty in individuals with MS and findings of extracranial venous anomalies consistent with CCSVI. Phase 1 was an open-label safety study of 10 subjects and phase 2 was a randomized, sham-controlled, double-blind study of 19 subjects (10 sham procedure, 9 treated). Both phases were 6 months in duration and enrolled individuals from June 2010 to March 2012. Study subjects were assessed at 1-, 3-, and 6-months post procedure with MRI, clinical and hemodynamic findings. Primary endpoints were safety at 24 hours and 1-month, venous outflow restoration greater than 75% at 1 month, and effect of angioplasty on new lesion activity and relapse rate over 6 months. There were no perioperative complications; however, 1 subject with a history of syncope required placement of a pacemaker prior to discharge due to episodic bradycardia. At 1 month post procedure, the Doppler evidence-based venous hemodynamic insufficiency severity score (VHISS) was reduced more than 75% compared to baseline in phase 1. In phase 2, higher MRI activity and relapse activity were identified as non-significant trends in the treated versus sham arm over 6 months. No differences in other endpoints were observed. The authors concluded that the procedure was reasonably safe, however "it failed to provide any sustained improvement in venous outflow as measured by duplex or clinical and MRI outcomes."

There have been various reports of serious adverse and potentially fatal events occurring as a result of venous angioplasty for the treatment of MS (Doepp, 2010; Kahn, 2010; Qui 2010). Khan (2010) states: "Any invasive endovascular procedures including angioplasty and venous stent placement should be discouraged until there is conclusive evidence to justify their indication in MS."

Mandato and colleagues (2012) evaluated the safety of ambulatory endovascular treatment in those with MS and CCSVI. A retrospective analysis was performed to assess complications occurring within 30 days of endovascular treatment of CCSVI. The study was comprised of 240 individuals and 257 procedures performed over 8 months. The indication for treatment was symptomatic MS. Primary procedures accounted for 93.0% (239 of 257) of procedures, and repeat interventions accounted for 7% (18 of 257). For individuals treated primarily, 87% (208 of 239) had angioplasty and 11% (26 of 239) had stent placement. Five individuals were not treated. Of those with restenosis, 50% (9 of 18) had angioplasty and 50% (9 of 18) had stent placement. Complications reported in the participants after the procedures included headache in 8.2% (21 of 257) and neck pain in 15.6% (40 of 57); 52.5% (21 of 40) of these individuals underwent stent placement. Three individuals experienced venous thrombosis requiring retreatment within 30 days. Sustained intra-procedural cardiac arrhythmias were observed in 3 individuals with 2 requiring hospitalization. The authors reported that the correlation between MS and CCSVI is a new theory and future research is needed in this area to show the effectiveness of endovascular treatment. This particular study demonstrated the risks of angioplasty and did not assess clinical outcomes after endovascular treatment of CCSVI.

The American Academy of Neurology does not currently address venous angioplasty for the treatment of MS or CCSVI in any of their current MS guidelines. The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) (2011) in a commentary on the treatment of CCSVI indicates there is a lack of evidence for the treatment of CCSVI, stresses the need for randomized trials and advises that this treatment should not be offered to those with MS outside of a well-designed clinical trial.

A matched-pairs pilot study by Arata and Sternberg (2014) described the use of a modified balloon angioplasty technique to the periadvential fibers of the internal jugular, azygos and left renal veins, referred to as transvascular autonomic modulation (TVAM), for treatment of cardiovascular autonomic nervous system (ANS) dysfunction (dysautonomia) to test angioplasty as a means improve ANS function in subjects with MS. The safety and efficacy of TVAM was compared to traditional balloon angioplasty. A total of 21 persons with MS with symptoms of cardiovascular ANS dysfunction underwent TVAM. Individuals in the TVAM group were compared to 21 individuals with MS in the same stages of the disease who underwent venous balloon angioplasty for the treatment of CCSVI. The effect of TVAM on ANS function was determined by assessing heart rate variability at baseline and 24 hours post intervention. The R-R interval values were higher for the TVAM group as compared to the control group, but failed to reach statistical significance for the majority of cardiovascular tests. The safety profile of both procedures was similar. The authors concluded that the safety and efficacy of TVAM in individuals with MS was encouraging as a treatment of dysautonomia in MS. Limitations noted for this study include a small sample size and a lack of long term and clinical impact.

Zamboni and colleagues (2018) released the results of the Brain Venous Drainage Exploited Against Multiple Sclerosis (Brave Dreams) trial. This multicenter, randomized, double-blind, sham-controlled, parallel-group trial evaluated the efficacy and safety of venous PTA for CCSVI in subjects with MS. There were 115 individuals included in this trial. Of those individuals, 76 were randomized to the PTA group and 39 were randomized to the sham group. A total of 112 individuals (97.4%) completed the trial including follow-up. The two primary end points at 12 months were a composite of functional impairments (walking control, balance, manual dexterity, postvoid residual urine volume, and visual acuity) and an MRI comparison at 6 and 12 months that evaluated the number of new combined cerebral lesions. Zamboni (2018) stated the following:

> The functional composite measure did not differ between the PTA and sham groups (41.7% vs 48.7%; odds ratio, 0.75; 95% confidence interval [CI], 0.34-1.68; p=0.49). The mean (SD) number of combined lesions on magnetic resonance imaging at 6 to 12 months were 0.47 (1.19) in the PTA group vs 1.27 (2.65) in the sham group (mean ratio, 0.37; 95% CI, 0.15-0.91; p=0.03: adjusted p=0.09) and were 1.40 (4.21) in the PTA group vs 1.95 (3.73) in the sham group at 0 to 12 months (mean ratio, 0.72; 95% CI, 0.32-1.63; p=0.45; adjusted p=0.45).

Due to these results, the authors concluded that venous PTA for CCSVI in individuals with MS is safe, but ineffective and, thus, not recommended. In 2020, Zamboni and colleagues expanded the Brave Dreams trial and published the results of a post-hoc analysis that evaluated the MRI imaging for the development of new lesions and assessed the activity of existing lesions of the 125 individuals that participated in the 12-month follow-up visit. Individuals with SPMS and RRMS that underwent venoplasty had decreased lesions at the 1-year follow-up when compared to those in the sham group (relative risk [RR] 1.42, 95% CI, 1.00-2.01; p=0.032). The expanded analysis also confirmed that the Giaquinta venography grading system may be helpful in future trials to determine optimal selection of individuals.

In 2019, Napoli and colleagues published the results of a randomized waitlist control study evaluating the efficacy of venous PTA in individuals with MS and CCSVI. A total of 66 individuals with MS and CCSVI were included with 31 allocated to the treatment group and 35 in the control group. The treatment group

received venous PTA immediately and the control group received venous PTA 6 months later. Efficacy of the treatment was measured using evoked potentials (EPs) tests, clinical-functional measures (CFMs), and upper limb kinematic measures (ULKMs). At the 1-month follow-up, 11 individuals (35%) in the treatment group had improved EPs and CFMs, and 9 individuals (29%) had improved ULKMs. The control group reported 7 individuals (20%) with improved EPs and CFMs, and 10 (29%) with improved ULKMs. The majority of each group had mixed results for all tests. The authors concluded that treatment with venous PTA improved some neurologic tests but "achieving disability improvement is unlikely" (Napoli, 2019). Limitations of this study include the small sample size, limited follow-up of 1 month, and the waitlist design.

Jagannath and colleagues (2023) in a Cochrane review, assessed the benefit and safety of venous PTA in individuals with MS and CCSVI. The review included 3 RCT's (n=238); 134 participants were randomized to the PTA group and 104 to sham treatment group. A moderate-quality evidence suggested that venous PTA did not increase the number of operative or post-operative serious adverse events compared with the sham procedure (RR 3.33, 95% CI 0.36 to 30.44; 3 studies, 238 participants); nor did it increase the number of participants who improved on a functional composite measure that included walking control, balance, manual dexterity, postvoid residual urine volume, and visual acuity over 12-month follow-up (RR 0.84, 95% CI 0.55 to 1.30; 1 study, 110 participants); nor did it reduce the rate of new relapses at six- or 12-month follow-up (RR 0.87, 95% CI 0.51 to 1.49; 3 studies, 235 participants). There was no effect of venous PTA on disability worsening at follow-up intervals 6, 11, and 12 months respectively. No difference in quality of life was reported between the treatment groups in two studies. Venous PTA was not effective in restoring blood flow assessed at one-month (1 study) or 12-month follow-up (1 study). The authors concluded that venous PTA does not provide a benefit in people with MS. The authors concluded that venous PTA has proven to be a safe technique, however in view of the available evidence of its ineffectiveness, this intervention cannot be recommended in people with MS. This was an update of a review first published in 2012, all ongoing trials were withdrawn or terminated and hence this updated review is conclusive. The authors stated that no further randomized clinical studies are needed.

At this time, evidence available in the peer-reviewed published literature does not support the use of venous angioplasty for the treatment MS, CCSVI, or dysautonomia, and use is not in accordance with generally accepted standards of medical practice. Recently published studies are limited by a small sample size and lack of randomization; furthermore, conflicting outcomes have been reported. Results from large randomized controlled clinical trials are needed to further assess the role of this modality in treating MS.

Ilio-femoral Venous Thrombosis and Chronically Occluded Iliac Vein

Treatment of chronically occluded iliac veins has typically consisted of endovenous bypass. Raju and colleagues (2009) reported on 167 post-thrombotic total iliac occlusions which had been treated with percutaneous recanalization. The procedure was reportedly successful in 129 of 167 limbs (83%). During a 48-month follow-up period, 39 out of 139 stented limbs (28%) occluded. A total of 17 of these individuals had patency restored but 7 later re-occluded. The 4-year secondary stent patency was 66%. While the majority of chronic total occlusions were successfully recanalized with very little morbidity, minimal downtime, sustained long-term stent patency, and substantial clinical improvement, one-third of the study subjects failed to maintain patency.

Kurklinsky and colleagues (2012) retrospectively analyzed 30-day, 1-year and 3-year patency of chronically occluded ilio-femoral venous thrombosis treated with stent placement in a case series from a single institution. Records of 189 consecutive individuals treated by interventional radiology for ilio-femoral venous occlusions between March 1, 2003, and December 1, 2008, were reviewed. A total of 89 cases of chronic iliac or ilio-femoral deep vein thrombosis without involvement of the inferior vena cava met criteria for analysis. All individuals (91 limbs) successfully underwent angioplasty with placement of venous self-expanding stents. Patency rate at discharge was 100%. Following the index procedure, mean pressure gradient across the lesion decreased from 5.63 mm Hg to 0.71 mm Hg. Median follow-up was 11.3 months (range, 0.8-72.4 months). Follow-up at 30 days demonstrated 90 of 91 limbs to be patent. Primary patency rates of treated limbs at 1 and 3 years were 81% and 71%, respectively. Primary patency was lost in 17 cases (19.1%); interventions to maintain or restore stent patency were performed in 13 cases (14.6%). Primary assisted limb patency rates at 1 and 3 years were 94% and 90%, respectively; secondary patency rate was 95%. The authors concluded that angioplasty with stent placement for treatment of chronically thrombosed ilio-femoral veins is a low-risk procedure with acceptable patency rates for as long as 3 years.

Cakir (2014) compared the efficacy of percutaneous aspiration thrombectomy (PAT) and standard anticoagulant therapy, and anticoagulation alone, for the treatment of acute proximal lower extremity DVT in a small, prospective randomized trial. A total of 42 individuals with acute proximal iliofemoral DVT were separated into 2 groups: an interventional treatment group (n=21) and an anticoagulation only treatment group (n=21). After starting standard anticoagulant therapy in the interventional group, PAT with large lumen catheterization was performed. Balloon angioplasty (n=19) and stents (n=14) were used to treat individuals with residual stenosis greater than 50% post PAT. Patency rates and clinical symptoms were evaluated in both the interventional and medical groups at 1, 3 and 12 months after treatment. At 12 months post treatment, the venous patency rates were 57.1% and 4.76% in the interventional and medical treatment groups, respectively. Additionally, a statistically significant improvement was noted in clinical symptom scores of the interventional group with or without stenting as compared to the medical group. The authors concluded that "PAT (with stenting if needed) is a safe and effective method when used to treat proximal DVT" and their findings "suggest that PAT can be used as an alternative treatment in proximal DVT patients."

Majeed and colleagues (2021) published a systematic review with meta-analysis evaluating the effectiveness at 1 year following endovascular stenting in individuals treated for symptomatic iliofemoral outflow obstruction with a dedicated venous stent. The main study outcomes included technical success, stent patency at 1 year, and symptom relief. The review included 49 studies involving 5154 individuals with non-thrombotic iliac vein lesions (n=1431), acute thrombotic (n=950), and post-thrombotic syndrome (PTS, n=2773). Technical success rates were comparable among groups (97% to 100%). There were no periprocedural deaths. Transient back pain was noted in 55% of individuals with PTS following intervention. Primary and cumulative patency at 1 year was: 96% and 100%, respectively, for non-thrombotic iliac vein lesions; 91% and 97%, respectively, for acute thrombosis; 77% and 94%, respectively, for PTS stents placed above the ligament; and 78% and 94%, respectively, for PTS stents placed across the ligament. There was insufficient data to compare patency outcomes of dedicated and nondedicated venous stents in individuals with acute thrombosis. In non-thrombotic iliac vein lesions and PTS, stent patency was comparable at 1 year. There was inconsistency in the use of validated tools for the measurement of symptoms

before and after intervention. When reported, venous claudication improved in 83% of individuals with PTS and 90% in those with non-thrombotic iliac vein lesions. Ulcer healing occurred in 80% of individuals with PTS and 32% of those with non-thrombotic iliac vein lesions. The findings suggest that dedicated venous stents perform comparably in terms of patency and clinical outcomes to non-dedicated technologies at 1 year for the treatment of non-thrombotic iliac vein lesions and PTS. However, there was significant heterogeneity between studies and there is a need for standardized criteria used for evaluating outcomes.

Razavi and colleagues (2015) performed a systematic review and meta-analysis of stent placement for the treatment of iliofemoral venous outflow obstruction. Data were extracted for multiple disease pathogenesis: nonthrombotic, acute thrombotic (AT) or chronic post-thrombotic (CPT). Main study outcomes included technical success, periprocedural complications (major bleeding, pulmonary embolism, death, and early thrombosis), relief of symptoms at final follow-up, and primary and secondary patency through 5 years. After initial screening for eligibility, 37 studies were included in the review. Technical success rates were comparable among all groups and ranged from 94% in the AT and CPT individuals to 96% in nonthrombotic individuals. The authors reported publication bias for technical success outcomes in AT subjects. Major complications were rare across all groups. Data for relief of symptoms were reported inconsistently. In the nonthrombotic and CPT studies, complete symptom relief at the final follow-up visit was reported for 69%-82% of individuals for pain, 64%-68% of individuals for edema, and 71%-81% of individuals for ulcer healing. Data for symptom relief were rarely reported in individuals with acute DVT. At 1 year follow-up, primary and secondary patency rates were 96% and 99% for nonthrombotic, 87% and 89% for AT, and 79% and 94% for CPT. Primary patency was usually evaluated by duplex ultrasound and a formal definition for primary patency was rarely provided. Inherent study limitations included that data was primarily derived from retrospective case series and there was a lack of complete data available for some comparisons.

Rollo and colleagues (2017) published a retrospective review of 105 individuals with symptomatic iliocaval venous occlusive lesions. The authors evaluated procedural technical success, clinical improvement, and primary and secondary 1-year patency in the 31 subjects (29.5%) that underwent venous stenting and met inclusion criteria. The results showed 100% of cases had technical success, an overall clinical improvement of 84%, and a primary and secondary 1-year patency success of 66% and 75% respectively using Kaplan-Meier cumulative analysis. The authors concluded that treatment of symptomatic iliocaval venous occlusive lesions with venous stenting is associated with successful 1-year patency; however, it was noted that the study had some limitations, including retrospective design and small sample size.

Williams and Dillavou (2020) published a systematic review of venous stents for the treatment of iliac and venacaval occlusive disease. A total of 23 studies met inclusion criteria with the majority using off-label stents and 3 studies using implanted dedicated venous stents. The median rate of ulcer healing in individuals treated with off-label stents was reported as 71% at 23.5 months; ulcer healing data was not reported in the dedicated stent studies. The median primary patency, primary assisted patency, and secondary patency were also measured at 23.5 months in the off-label stent studies and the results were 71%, 89%, and 91%, respectively; the dedicated stent studies reported 78.8% was the mean primary patency at 12 months. Complication rates were reported as a mean and median of 3.0% and 3.4 %, respectively for the off-label stents; no mortality or pulmonary embolisms were reported. This systematic review highlighted that the quality of evidence remains low for the indication of iliac and

venacaval occlusive disease. Though there is some benefit of ulcer healing and reduction of pain reported by the off-label stent studies, additional research is warranted to determine the benefits and the risk of complications associated with both off-label and dedicated stents.

TORPEDO (Thrombus Obliteration by Rapid Percutaneous Endovenous Intervention in Deep Venous Occlusion) Trial

In a randomized controlled trial, Sharifi and colleagues (2010) compared the safety and efficacy of percutaneous endovenous intervention (PEVI) and anticoagulation versus anticoagulation alone in the reduction of venous thromboembolism (VTE) and post-thrombotic syndrome (PTS) in acute proximal deep venous thrombosis (DVT). A total of 183 individuals with symptomatic proximal DVT were randomized over a 30-month period beginning in February 2007 to receive either PEVI plus anticoagulation, or anticoagulation alone. PEVI consisted of one or more of a combination of thrombectomy, balloon venoplasty, stenting, or local low-dose thrombolytic therapy. In the PEVI group, 68 persons received a balloon venoplasty and 47 stents were placed in 27 persons. Anticoagulation consisted of intravenous unfractionated heparin or subcutaneous low-molecular weight heparin plus warfarin. At 6 months follow-up, recurrent VTE developed in 2 of 88 persons of the PEVI plus anticoagulation group versus 12 of 81 of the anticoagulation-alone group (2.3% vs. 14.8%, p=0.003). PTS developed in 3 of 88 persons of the PEVI plus anticoagulation group and 22 of 81 of the anticoagulation-alone group (3.4% vs. 27.2%, p<0.001). The authors concluded that PEVI plus anticoagulation may be superior to anticoagulation alone in the reduction of VTE and PTS at 6 months and in reducing length of hospital stay and signs and symptoms of DVT.

Follow up results of the TORPEDO trial were reported by Sharifi and colleagues in 2012. Over a mean follow-up of 30±5 months (range 12-41), 3 persons were lost to follow up and there were 11 deaths (5 PE, 6 cancer) which left 88 of 91 persons in the PEVI group and 81 of 92 in the control group. PTS developed at a significantly higher rate in the control group compared to the PEVI group [6 (6.8%) of the PEVI plus anticoagulation group vs. 24 (29.6%)] of the anticoagulation only group (p<0.001). Recurrent VTE developed in 4 (4.5%) of the 88 PEVI plus anticoagulation individuals vs. 13 (16%) of the 81 individuals receiving anticoagulation only. The authors concluded that PEVI in persons with proximal DVT appears to be superior to anticoagulation alone in the reduction of VTE and PTS. This benefit extended to more than 30 months.

CaVenT Study

Many persons receiving conventional anticoagulant treatment for acute DVT develop post-thrombotic syndrome (PTS). In an open-label, randomized controlled trial, Enden and colleagues (2012) examined whether additional treatment with catheter-directed thrombolysis (CDT) using alteplase reduced the development of PTS. A total of 209 persons aged 18-75 years with a first-time iliofemoral DVT were recruited from various Norwegian hospitals. Study individuals were randomized within 21 days from symptom onset to conventional anticoagulant treatment alone or additional CDT. Two co-primary outcomes were assessed: frequency of PTS as assessed by Villalta score at 24 months, and iliofemoral patency after 6 months. A total of 209 participants were randomly assigned to treatment groups (108 control, 101 CDT). At completion of 24 months' follow-up, data for clinical status was available for 189 individuals (90%; 99 control, 90 CDT). At 24 months, 37 (41.1%) individuals allocated additional CDT presented with PTS compared to 55 (55.6%) in the control group. The difference in PTS corresponded to an

absolute risk reduction of 14.4%, and the number needed to treat was 7. Iliofemoral patency after 6 months was reported in 58 individuals (65.9%) on CDT versus 45 (47.4%) on control. CDT improved clinically relevant long-term outcomes after iliofemoral DVT by reducing PTS compared with conventional treatment. Study limitations included possible local differences due to four different centers having performed the interventions as well as the possibility of bias due to the open-label design of the study.

In a sub analysis of the CaVenT Study, Haig and colleagues (2012) evaluated potential markers for early and long-term efficacy of CDT, adverse events, and their interrelationship. Individuals aged 18-75 years (mean, 54 y; 33 women) with first-time proximal DVT and symptoms up to 21 days were included in an open, multicenter, randomized, controlled trial (CaVenT study). The authors reported on the 92 individuals who received CDT procedures after allocation to the CDT arm in the CaVenT study. The DVT diagnosis was verified by ultrasound or by supplementary venography or CT venography. Anticoagulant therapy was initiated with low molecular weight heparin. CDT was initiated the next working day, and low molecular weight heparin was subsequently stopped. Adjunctive balloon angioplasty and stent insertion were performed at the operator's discretion to obtain flow and stenosis of less than 50%. Adjunctive balloon angioplasty was performed in 40 individuals. Five individuals, (3 women and 2 men) were diagnosed with May-Thurner syndrome (iliac vein compression) and treated with adjunctive angioplasty, 2 with a balloon only and 3 with stents.

A mean clot resolution of 82%±25 was achieved in 92 individuals. Successful lysis (≥50%) was obtained in 83 persons. Early efficacy was equal for femoral and iliofemoral thrombus and not related to thrombus load before CDT, symptom duration, or predisposing risk factors. Lower thrombus score at completion of CDT was associated with increased patency at 24 months ($p=0.040$), and increased patency after 6 and 24 months was correlated with reduced development of PTS after 24 months ($p<0.001$). The authors concluded that CDT via popliteal access appeared to safely and effectively remove clots and restore iliofemoral patency. No baseline characteristics were associated with early efficacy or PTS after 24 months.

The Society of Interventional Radiology 2009 position statement on the treatment of acute iliofemoral deep vein thrombosis with use of adjunctive catheter-directed intrathrombus thrombolysis states:

> The Society of Interventional Radiology (SIR) supports the use of anticoagulant therapy for DVT and the use of adjunctive CDT or surgical thrombectomy for patients with limb-threatening phlegmasia. SIR is aware of the controversy within the medical community regarding the use of adjunctive CDT for patients with acute DVT who do not exhibit signs of impending circulatory compromise. SIR recognizes the methodologic limitations of the studies supporting CDT and strongly believes that the execution of a multicenter randomized trial to conclusively quantify the risk–benefit ratio of CDT in patients with acute proximal DVT should be considered an important national health care priority. In the meantime, physicians are still obligated to carefully consider the short-term and long-term consequences of DVT and to recommend the best possible overall treatment strategy to patients based on the currently available, albeit imperfect, evidence. Although there are no large, randomized trials to mitigate for or against CDT, the preponderance of the available evidence favors the existence of a clinical benefit to adjunctive CDT for the subset of patients with acute iliofemoral DVT.

The American Heart Association (2011) Recommendations for Percutaneous Transluminal Venous Angioplasty and Stenting, state:

1. Stent placement in the iliac vein to treat obstructive lesions after CDT, PCDT, or surgical venous thrombectomy is reasonable (Class IIa; Level of Evidence C).
2. For isolated obstructive lesions in the common femoral vein, a trial of percutaneous transluminal angioplasty without stenting is reasonable (Class IIa; Level of Evidence C).
3. The placement of iliac vein stents to reduce PTS symptoms and heal venous ulcers in patients with advanced PTS and iliac vein obstruction is reasonable (Class IIa; Level of Evidence C).
4. After venous stent placement, the use of therapeutic anticoagulation with similar dosing, monitoring, and duration as for IFDVT patients without stents is reasonable (Class IIa; Level of Evidence C).
5. After venous stent placement, the use of antiplatelet therapy with concomitant anticoagulation in patients perceived to be at high risk of rethrombosis may be considered (Class IIb; Level of Evidence C).

(Class IIa: Benefit >> risks, Additional studies with focused objectives needed, it is reasonable to perform procedure or administer treatment. Class IIb: Benefit ≥ risks, additional studies with broad objectives needed, additional registry data would be helpful. Procedures/treatment may be considered. Evidence C: very limited populations evaluated, only consensus opinion of experts, case studies or standards of care.)

In 2022, the clinical practice guidelines on the management of chronic venous disease of the lower limbs were updated by the European Society for Vascular Surgery (ESVS) (De Maeseneer, 2022) to include the following recommendations:

- In patients with clinically relevant chronic iliocaval or iliofemoral obstruction or in patients with symptomatic non-thrombotic iliac vein lesions, percutaneous transluminal angioplasty and stent placement using large self-expanding stents should be considered. (Class IIa, level B)
- Percutaneous transluminal angioplasty is not recommended as a single treatment for patients with chronic deep venous obstruction. (Class III, level C)
- After percutaneous transluminal angioplasty, stent placement should be considered for patients with chronic deep venous obstruction. (Class IIa, level C)

(Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy. Class III: Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful. Level B: Data derived from a single randomized clinical trial or large non-randomized studies. Level C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries.)

Emerging studies may suggest improved patency and decreased post thrombotic complications. However, these studies are limited in not isolating the unique contribution to patency and improved outcomes of angioplasty, instead reporting out improvements with angioplasty as one of several catheter directed therapies.

Idiopathic Intracranial Hypertension (IIH)

IIH is also referred to as pseudotumor cerebri or benign intracranial hypertension. It is characterized by an increase in intracranial pressure (ICP) in the absence of an identifiable cause and may lead to severe headaches and vision loss. The incidence of IIH is higher in young obese women as compared to the general population. Treatment typically includes weight loss, medications (including acetazolamide, topiramate, and furosemide), and in some cases, optic nerve sheath fenestration (ONSF) or cerebrospinal fluid (CSF) diversion procedures such as ventriculoperitoneal shunting (VPS) and lumboperitoneal shunting (LPS). Venous sinus stenting has been proposed as a treatment option for IIH, based on the observation that many individuals with IIH have apparent stenoses of the transverse venous sinus or other cerebral veins.

IHH is diagnosed according to the modified Dandy criteria (Friedman, 2002), which states the following:

- Symptoms and signs of increased intracranial pressure (e.g., headache, transient visual obscurations, pulse synchronous tinnitus, papilledema, visual loss)
- No other neurologic abnormalities or impaired level of consciousness
- Elevated intracranial pressure with normal cerebrospinal fluid (CSF) composition (generally, greater than 250 mmH_2O)
- A neuroimaging study that shows no etiology for intracranial hypertension
- No other cause of intracranial hypertension apparent

Raynald and colleagues (2022) published a prospective, single center, case-controlled study of 181 individuals comparing medical treatment (n=121 [69%]) to stenting (n=60 [33.1%]) with a 6-month follow. Compared with the medical treatment group, the stenting group had a higher prevalence of visual disturbances (86.8% vs. 70%, p=0.007) and papilledema (89.3% vs. 63.3%, p<0.001). CSF pressure was higher in the stenting group than in the medical treatment group (311.7 mmH_2O vs. 282.3 mmH_2O, p=0.001). Additionally, the stenting group stenosis rate (75.5% vs. 70.9%, p=0.010) and pressure gradient (15.0 mmH_2O vs. 11.0 mmH_2O, p=0.001) was higher than in those receiving medical treatment. Individuals undergoing stenting had rapid signs of improvement in both their symptoms and papilledema compared to the control group. The author's concluded papilledema is the most distinguished symptom associated with increased ICP.

Kalyvas and colleagues (2021) published a systematic review of the efficacy and complication profile of surgical options for IIH including venous sinus stenting, ONSF, CSF diversion procedures, and bariatric surgery. The review included 2302 participants across 109 studies of which none were RCTs. The mean follow-up time was approximately 20 months. Venous sinus stenting improved papilledema, visual fields, visual acuity, and headaches in 87.1%, 64.6%, 72.7%, and 72.1% of participants, respectively. The strategy had a 12-month failure rate of 13.1% with symptom relapse due to sinus restenosis leading to supplementary intervention in 3.4% (28 out of 825) of participants. Though only 9.4% of participants experienced complications, major complications occurred in 19 (2.3%) participants including a case of bilateral cerebellar hematoma, obstructive hydrocephalus and death attributed to venous perforation by a large guide wire. By comparison, ONSF and CSF diversion resulted in similar visual field improvements of 65.2% and 66.8%, but only improved visual acuity by 44.1% and 55%, respectively.

Participants who underwent ONSF showed the most improvement in papilledema (90%), but the least improvement in headaches (49.3%). While CSF diversions provided immediate improvement of headache or visual defects, they also had a high 12-month failure (39.1%), complication (44.1%), and severe complication rate (9.4%) with a mean 2.6 revisions per participant. ONSF was effective at halting visual deterioration, but the strategy had limited effects on headache resolution and a complication rate of 20%. The evidence suggests that venous sinus stenting provides promising combined results for headache resolution and visual outcomes with lower failure rates. However, the strategy carries severe, though infrequent, risks. The review is limited as only 3 of the 47 studies included on venous sinus stenting were prospective and 2 of those 3 were by the same group with overlapping participants. Additionally, participant selection was inconsistent between studies due to a lack of standardized criteria for recommending venous sinus stenting.

Lee and colleagues (2021) published a retrospective review of 47 individuals with known or suspected diagnosis of IIH who had cerebral venography with manometry followed immediately by lumbar puncture to correlate venous sinus pressure and opening pressures (OP). The results showed 20 individuals (42.6%) were found to have trans-stenosis gradient of 8 mmHg or greater, 17 subjects with OP < 20 cm H_2O (36.2%), mean superior sagittal sinus pressures (SSS) of 13.5 (4.2) mmHg, and torcular pressures of 15.4 (6.7) mmHg. The authors suggest normal superior sagittal sinus pressures should measure < 18 mmHg (80th percentile) in non-pathologic conditions. They concluded that lumbar puncture OP significantly predicted transverse sinus ($p<0.001$), torcular ($p<0.001$), and SSS ($p<0.001$).

Leishangthem and colleagues (2019) published a systematic review with meta-analysis of 29 studies involving 410 participants who underwent dural venous sinus stenting (DVSS) for refractory IIH focusing on success rates, complications, and re-stenting rates. None of the included studies were RCTs and 8 reports involved a single participant. The mean follow-up time was 22.4 months. The investigators found that DVSS in appropriately selected individuals with refractory IIH was associated with a high technical success rate of 99.5%, low rates of repeated procedures (10%), and a low major complication rate of 1.5%. Criteria for DVSS placement varied across institutions but generally included: individuals with refractory IIH with progressive symptoms or vision loss; obstructive venous outflow pattern (isolated sigmoid sinus stenosis, bilateral transverse/sigmoid sinus stenosis, and ipsilateral transverse/sigmoid sinus stenosis with contralateral transverse/sigmoid sinus hypoplasia or absence); and a direct pressure gradient across the target stenotic lesion >8 mmHg. There was a 92% improvement in papilledema, an 82% improvement in headaches, and a 78% improvement in visual acuity. The total complication rate was 4.9% and largely related to access site complications. The major complications included intracranial hemorrhage, subdural hematoma, and intracranial bleeding. Intraprocedural stent migration occurred in 1 participant without complication. No mortality was found directly related to DVSS. The mean pre-stent pressure gradient was 18.1±9.5 mmHg which decreased to 2.8±3.1 mmHg after stent placement. There were 64 stents placed in the right transverse sinus, 23% in the left transverse sinus, and 13% were placed bilaterally. There were 41 participants that required re-stenting, 17 stented adjacent to the initial stent, 5 contralateral stents, and 5 were re-stented secondary to in-stent stenosis. Treatment failure requiring the need for another treatment modality occurred in 10 of 410 participants (2.4%). The studies all used self-expanding stents meant for other indications. The authors of the review suggest using stents dedicated to this procedure, and balloon expanding stents in the case of extrinsic stenosis may result in reduced complications. The results of this review add to the evidence supporting DVSS for

individuals with refractory IIH, but uniform criteria for selecting individuals who are most likely to benefit from the intervention and standard procedural tools have yet to be described in prospective controlled trials.

A systematic review and meta-analysis evaluating the use of venous stenting in individuals with IIH was published by Nicholson and colleagues in 2019. The systematic review yielded 20 studies from 18 centers with a total of 474 individuals. Of the 20 studies, 14 were retrospective and 6 were prospective observational. The largest number of study participants in a single study was 52, while the smallest had 6 participants. All studies were performed at a single center and the mean follow-up period was 18 months. The overall improvement or resolution of headache was 79.6% (95% CI, 73% to 85.9%), while overall rate of improvement in papilledema was 93.7% (95% CI, 90.5% to 96.9%). Pulsatile tinnitus resolved in 90.3% (95% CI, 83.8% to 96.7%). While the meta-analysis had positive results including an overall rate of recurrence of IIH symptoms after stenting of 9.8% (95% CI, 6.7% to 13%) and a rate of major complications of 1.9% (95% CI, 0.07% to 3.1%), there are limitations to these results including a lack of comparison group and randomization in the included studies, small sample sizes, and lack of a standardized tool for clinical evaluation of headache in the included studies.

Saber and colleagues (2018) published a systematic review with meta-analysis of 24 studies involving 473 participants assessing the clinical outcomes as well as stent survival and stent adjacent stenosis rates in individuals undergoing DVSS for refractory IIH. The studies ranged in size from 4 to 52 participants. The mean follow-up time was 18.3 months. Headache, papilledema, visual acuity, and tinnitus improved in 256/330 (77.6%), 247/288 (85.8%), 121/172 (70.3%), and 93/110 (84.5%) of participants, respectively. The authors reported that venous stenting was associated with significant reduction in pressure gradients and a reduction in pressure gradients was significantly correlated with symptom resolution, but did not provide statistics. The minimum pressure gradient required for stent placement varied across studies from 0 mmHg to >15 mmHg in studies where it was reported. The average pressure gradient before stenting was 20 mmHg and the average final pressure gradient after stenting was 3.2 mmHg. The stent survival rate was considered acceptable at 84% (95% CI, 79% to 87%). Stent adjacent stenosis rate was 14% (95% CI, 11% to 18%) and was the major reason for stent revisions. The authors commented that stent adjacent stenosis may be a result of factors outside of the area of stenting and that focal stenoses may not result in stent adjacent stenosis. The rate of major neurological complications was <2%. The results of this review indicate that venous sinus stenting leads to symptom resolution in carefully selected individuals. However, heterogeneous enrollment criteria makes it difficult to understand which individuals are most likely to benefit from this procedure. Further studies are needed to identify determinants of stent-adjacent stenosis and stent survival.

Satti and colleagues (2015) published a meta-analysis comparing ONSF, CSF diversion, and venous sinus stenting in individuals with refractory IIH with a focus on symptom improvement, complications, and the need for repeat procedures. The analysis included 18 studies (n=712 participants) on ONSF with a mean follow-up of 21 months, 17 studies (n=435 participants) on CSF diversion procedures with a mean follow-up of 41 months, and 8 studies (n=136 participants) on venous sinus stent placement with a mean follow-up of 22.9 months. Headaches were most improved by venous sinus stenting (83%) compared to CSF diversion procedures (80%) or ONSF (44%). Papilledema was also most improved after venous stent placement (97%) compared to CSF diversion (70%) or ONSF (80%). Visual acuity improved or remained stable in 95% and visual fields improved in 68% of participants that underwent ONSF. In venous sinus stenting and CSF diversion procedures, visual acuity and visual fields were combined and described as visual acuity changes. There was an improvement in visual acuity changes of 54% after

CSF flow diversion compared to 78% after venous sinus stent placement. The rate of major complications was highest for CSF diversion procedures (7.6%) followed by venous stent placement (2.9%), and lowest for ONSF (1.5%). No fatalities were reported for any procedure. The rate of minor complications (4.4%) and repeat procedures (10.3%) was lowest for venous sinus stent placement and highest for CSF diversions at 32% and 43%, respectively. There were 8 participants that required subsequent stent placement at or near the original stent due to restenosis. Nearly all stents placed were self-expanding nitinol stents from a variety of manufacturers with <5% of studies describing placement of balloon-mounted stents. The authors identified that there are three patterns of dural venous sinus stenosis on non-invasive imaging, magnetic resonance venography, that may be amenable to stenting: focal stenosis of the superior sagittal sinus, bilateral transverse/sigmoid sinus stenosis, and unilateral transverse/sigmoid sinus stenosis with contralateral hypoplasia/aplasia. They also noted that surgical interventions for refractory IIH are performed by different specialties making the collected data inconsistent. The results indicate that carefully selected individuals with refractory IIH benefit from venous sinus stent placement. However, the lack of standardized data collection and randomized studies directly comparing surgical methods makes it difficult to identify individuals who are most likely to benefit from this intervention.

Lai and colleagues (2014) published a systematic review with pooled analysis comparing the therapeutic efficacies of available interventions for refractory IIH. The review included 30 studies involving 332 participants treated with ONSF, 287 participants with LPS, 61 with VPS, and 132 participants with DVSS. Participants were considered for stent placement when there was angiographic evidence of focal dural sinus stenosis with a pressure gradient of >8 mmHg between the proximal and distal ends of stenosis. The Headaches and visual acuity were most improved following stent placement (82.9% and 84.6%, respectively) and least improved after ONSF (36.5% and 49.3%, respectively). The highest rate of per-procedural complications was associated with CSF shunting procedures with a mean number of 2.4 VPS and 3.6 LPS surgeries per participant. In the pooled stent cohort, there were 3 participants (2.3%) with significant neurological complications that made a full postoperative recovery. The review was limited by a lack of reporting uniformity, participant selection, and a direct within study comparison of treatment modalities.

Teleb and colleagues (2013) published a systematic review with analysis assessing the outcomes of individuals undergoing DVSS for the treatment of IIH. The review included 19 studies involving 207 individuals with medically or surgically refractory IIH, headache, and elevated ICP. None of the included studies were RCTs. The authors reported an overall symptom improvement rate of 87% and technical success was achieved in more than 95% of participants. After stent placement, there was a resolution or improvement of 81% of headaches and 87% of papilledema. Sinus pressure decreased from an average of 30.3 mmHg to 15 mmHg. The sinus pressure gradient decreased from 18.5 mmHg to 3.2 mmHg. There was a low rate of major complications directly related to stent placement (1.5%) that included vein perforation leading to subdural hematoma, retroperitoneal hematoma, and transient contrast extravasation. The need for retreatment ranged from 0% to 33% across studies. The analysis indicates objective findings such as CSF pressures, papilledema, and pressure gradients across stenosis resolve after stenting, while subjective findings such as headaches improve but do not resolve. Importantly, participant selection and anticoagulant therapy across studies lacked standardization. Additionally, a lack of long-term follow-up compared to other surgical strategies could skew the observed presence of complications. Prospective randomized trials are needed to appropriately characterize the ideal candidates for this intervention.

The significance of pressure gradients across stenotic lesions in individuals with IIH has been the focus of some systematic reviews. Starke and colleagues (2015) published a systematic review of literature in which they recommended venous sinus stenting for refractory IIH in individuals with radiographic evidence of venous sinus stenosis and a physiologic pressure gradient, as a Class IIa recommendation with a Level of Evidence of C due to its favorable risk-to-benefit profile. However, the optimal pressure gradient indicating the need for stenting has not been defined. McDougall and colleagues (2018) conducted a systematic review aimed at identifying individuals with IIH who benefit from DVSS on pressure gradients of their venous sinus stenosis. The review included 32 studies involving 186 participants. Those with favorable outcomes had higher mean pressure gradients (22.8±11.5 mmHg vs 17.4±8 mmHg, p=0.033) and higher changes in pressure gradients after stent placement (19.4±10 mmHg vs 12±6 mmHg, p=0.006) compared with those with unfavorable outcomes. Post-stent pressure gradients were not significantly different between groups (p=0.934). The change in pressure gradient with stent placement was found to be an independent predictor of favorable outcomes (p=0.028). Of individuals with a pressure gradient >21 mmHg, 94.2% (81/86) achieved favorable outcomes compared to 82% (82/100) with a gradient <21 mmHg (p=0.022). While there appears to be a relationship between the success of venous sinus stenting and the pressure gradient across stenoses, there was no agreement on the definition of what constitutes a pathologically elevated pressure gradient or the conditions under which that gradient is obtained. The authors also noted that there may be outcome differences between individuals with focal stenotic lesions and those with longer segment stenosis. The findings underscore the need for prospective, randomized trials evaluating venous sinus stenting for IIH.

A few prospective case series have reported findings on the use of venous sinus stenting in individuals with IIH. Dinkin and colleagues (2017) published a case series of 13 individuals with refractory, treatment-intolerant, or fulminant IIH who underwent venous sinus stenting. Only individuals with >50% bilateral venous sinus stenosis at the transverse-sigmoid sinus junction and an elevated trans-stenotic pressure gradient ≥8 mmHg were considered. Stenting resulted in a reduction of the trans-stenotic gradient from a mean of 20.54 mmHg to 2.8 mmHg, and a reduction in ICP which was associated with an improvement in papilledema, retinal nerve fiber layer thickness, visual field parameters, headache, and tinnitus. No participants reported a worsening of symptoms, and no serious adverse events were reported. Liu and colleagues (2017) published a case series evaluating the effects of venous sinus stenting in 10 participants with refractory IIH and venous sinus stenosis. Individuals with an elevated ICP and significant pressure gradient were offered stent placement, but the level indicating a significant gradient was undefined. A total of 9 participants had objective and subjective clinical improvement of status. There was one individual with initial clinical improvement that later declined who was found to have stent-adjacent stenosis. There were 2 participants found to have stent-adjacent stenosis who were retreated with a subsequent stent that resulted in a resolution of symptoms. Donnet and colleagues (2008) published a case series of 10 individuals with refractory IIH who were treated with venous sinus stenting performed with or without angioplasty. Headaches improved or resolved in 8 of 10 participants. Papilledema and pulsatile tinnitus resolved in all participants that presented with it at baseline. No serious complications after stenting were reported. Higgins and colleagues (2003) published a case series of 12 individuals with refractory IIH undergoing venous sinus stenting. Over half of the participants had a prior surgical intervention for IIH. Notably, the authors indicated that 1 individual refused any further LPS, and many individuals had developed a severe aversion to the procedure. All participants had a reduction in ICP though it was not necessarily accompanied by clinical improvement. One participant with a 12-year pre-stent symptom duration had a reduction in sagittal sinus pressure of 7 mmHg with no clinical improvement. In another with a similar duration of symptoms, the pressure was reduced by 12 mmHg with a resolution of symptoms. The findings

suggest that venous outflow obstruction may not have been the cause of IIH in those without clinical improvement, as dilating the stenosis and eliminating the pressure gradient should have been curative. The heterogeneous group of participants limited the ability to identify criteria to predict good outcomes after stenting.

Shields and colleagues (2019) published a retrospective observational study investigating the outcomes of venous sinus stenting in individuals with IIH. The study involved 42 individuals who demonstrated a significant pressure gradient across the transverse-sigmoid junction of >5 mmHg and underwent venous sinus stenting. The mean follow-up period was 25.6 months. All participants had headaches, visual disturbances, and papilledema. A total of 18 individuals had complete resolution of headaches and 22 remained in care for chronic migraine and other headaches, 7 of which also lacked resolution of papilledema. Of the 39 individuals that underwent post-stent ophthalmologic evaluations, 29 had resolution of papilledema (74%). Complications included a need for additional surgical treatments (n=6), disease progression and stenosis either proximally or distal to initial stent requiring re-stenting (n=2), and in-stent thrombosis at 1 month post-op possibly due to placement error of the original stent (n=1). The authors note that there is overlap between the features of headaches associated with IIH and chronic migraines which may account for the high number of individuals who continued to experience them after treatment. The authors concluded the success rate of the intervention as 74% (95% CI, 57.5% to 86.4%) based on a resolution of papilledema in the same percentage of cases. The analysis of outcomes in this study is limited by a lack of uniform pre- and post-stent visual field testing and post-stent pressure gradient assessment across all included individuals.

Raper and colleagues (2018a) published a retrospective review involving 47 individuals with IIH and intracranial venous stenosis who underwent venous sinus stenting aimed at classifying the subsequent changes in pressure gradient and identifying predictors of stent-adjacent stenosis. The most common location of stenosis was the transverse sinus-sigmoid sinus junction (63.3%) and the transverse sinus (32.6%). Type 1 gradient resolution, in which the mean venous pressure (MVP) in the transverse sinus decreases towards the MVP in the sigmoid sinus, occurred in 18 individuals (38.3%). Type II gradient resolution, in which sigmoid sinus MVP increases towards that in the transverse sinus, occurred in 7 individuals (14.9%). Type III gradient resolution, in which MVP equilibrates to a middle value, occurred in 22 individuals (46.8%). Stent-adjacent stenosis occurred in 0%, 28.6%, and 22.7% of individuals with type I, II, and III gradient resolutions, respectively. There was no significant association between the development of stent-adjacent stenosis and those in whom the maximum MVP remained >20 mmHg after stent placement (p=0.272). Pattern of resolution and not absolute pressure value was the significant factor, with type II (p=0.0181) and type III (p=0.0306) patterns being most associated with the development of stent-adjacent stenosis. The results indicate that evaluation of these patterns may help predict stent-adjacent stenosis, with type I pattern representing an ideal response to venous sinus stenting. The authors suggest that those with type II and type III patterns may benefit from longer initial stent constructs, particularly if they have other predictors of recurrent stenosis. The study was limited by the low quantity of stent-adjacent stenosis which only occurred in 7 of the 47 individuals that underwent a stent procedure and retrospective design.

Asif and colleagues (2018) published a single-center retrospective case series investigating the outcomes and efficacy of DVSS at 3 to 4 month follow-up in 41 individuals with refractory IIH. DVSS was the primary procedure for 26 individuals and second-line procedure for 15 individuals. Individuals were offered DVSS or CSF diversion if they had stenoses with a significant pressure gradient. A pressure gradient of 8 mmHg was considered significant.

The mean pre-stent superior sagittal sinus pressure was 28.2 mmHg reduced to 17.5 mmHg at 3 to 4 month follow-up. The investigators found objective evidence of the effectiveness of venous sinus stenting in radiographic stenosis obliteration in 80.8% in the primary group and 80% in the secondary group. There was a 65% participant-reported subjective improvement or resolution of headaches, and a 63.3% objective improvement in papilledema. Treatment did not result in a universal improvement of visual outcomes. The retreatment rate of 12.2% at 120 days was better compared to VP shunts where failure rates range from 23% to 46.3%, though over a longer period of observation. Complications included: 2 individuals (4.9%) that suffered in-stent thrombus formation with a recurrence of symptoms; stenosis outside the placed stent requiring treatment in 3 individuals (7.3%); and 3 individuals who developed ipsilateral radiographic stenosis distal to the initial stent without the need for retreatment. The authors noted that the presence of a significant pressure gradient across stenosis defines functionally significant stenosis, critical for the selection and management of individuals. They also noted that there may be distinct entities under the diagnosis of IIH that may need subclassification such as DVSS-responsive and DVSS-unresponsive disease. The main contributor to raised ICP may be a focal intramural venous sinus stenosis in stent-responsive IIH and multifactorial in stent-unresponsive IIH. While there was some clinical improvement following stent insertion, the findings are limited by a lack of direct comparison. Further investigation is needed comparing outcomes of venous sinus stenting and CSF diversion and to identify factors associated with restenosis.

A retrospective analysis (Puffer, 2013) assessed outcomes of 143 cases of venous sinus angioplasty with stent placement performed for IIH with a mean follow-up of 22.3 months and reported “promising” results. However, due to sparse documentation of clinical benefit as well as determining ideal population for treatment, additional evaluation with long-term follow-up is needed.

Ahmed and colleagues (2011) published a retrospective case series involving 52 individuals with refractory IIH treated with stent placement for transverse sinus stenosis. The mean duration of symptoms prior to stenting was 23 months. A pressure gradient across the transverse sinus stenosis of >8 mmHg was chosen as a cutoff between normal and abnormal based on center experience. The mean superior sagittal sinus pressure decreased from 34 mmHg to 16 mmHg, and pressure gradient decreased from 20 mmHg to <1 mmHg in those with papilledema (n=46). In those without papilledema, the superior sagittal sinus pressure decreased from 25 mmHg to 12 mmHg and the pressure gradient decreased from 11 mmHg to 0 mmHg. IIH symptoms resolved in 49 of 52 participants. Papilledema and pulsatile tinnitus resolved in all participants that presented with it. Headaches improved in 81% of participants. There were 5 participants requiring multiple stents at their first stent procedure, 1 had intrinsic stenosis and 4 had extrinsic compression. A repeat stenting procedure was required in 6 cases, all of which had a relapse of symptoms and recurrent stenosis adjacent to the previous stent. These cases were treated early in the series. As the study progressed, the investigators believed that long extrinsic stenoses should have longer stents at the time of initial placement and that resulted in fewer instances of repeat stenting. There were 2 participants with significant complications which included a subdural hematoma that resulted when a guidewire perforated a vein, and a subdural subarachnoid and intracerebral bleed which occurred at the time of emergency treatment for fulminant IIH. Both participants fully recovered. The findings show that carefully selected individuals with IIH and transverse sinus stenosis may benefit from venous sinus stenting. However, the study was limited by a lack of a control comparison, standardized stent selection, retrospective design, and a mean follow-up of 2 years.

Additional smaller studies have reported the results of venous sinus stenting in individuals with refractory IIH. Fields and colleagues (2013) reported a 67% improvement or resolution in headaches, stabilized or improved visual acuity (92%), resolved tinnitus in 79% of participants, no major complications, and no instances of restenosis among those with follow-up data (14 individuals). Higgins and colleagues (2002) reported the case of a single individual in which papilledema resolved, though a mild headache persisted at the 1-year follow-up. The case helped establish a correlation between pressure gradients and the clinical features of IIH. Larson and colleagues (2021) found that the use of a single stent provided some venous decompression of contralateral non-stented stenosis and was effective at resolving papilledema, but some individuals continued to have persistent headaches. This suggests that unilateral transverse-sigmoid sinus stenting may be effective for some but not all symptoms of IIH. Raper and colleagues (2018b) concluded that maximum post-stent MVP, clinical outcomes, and stent-adjacent stenosis requiring retreatment after venous sinus stenting were not significantly associated with BMI. The studies had several limitations. The pressure gradient of significance across these studies was either unreported or varied from >8 mmHg. Mean follow-up ranged from 3.6 months to 14 months in those with available data. They were all single center studies. In the study on BMI associations (Raper, 2018b), weight measurements were not obtained at follow-up, a potential confounder for the assessment of outcomes. Other studies have published comparable results (Matloob, 2017; Patsalides, 2020; Shazly, 2017). All authors concluded venous stenting offers a treatment option for carefully selected individuals with IIH; however, study limitations included small sample sizes and study designs.

Buell and colleagues (2017) reported on a case of a single individual who developed an intracranial dural arteriovenous fistula after venous sinus stenting for IIH and was treated with a repeat stent placement. The authors hypothesize that the type of stent used may have contributed to the result. Lavoie and colleagues (2018) reported the case of a single individual who developed severe cerebellar hemorrhage following transverse sinus stenting. Their findings suggest that risks could be reduced using stent systems designed for this approach as those used in these case were designed for large extracranial arteries.

An international panel along with four national professional bodies, the Association of British Neurologists, British Association for the Study of Headache, the Society of British Neurological Surgeons, and the Royal College of Ophthalmologists (Mollan, 2018) issued consensus guidance for the management of IIH. The guidance included the following statements:

- The role of neurovascular stenting in IIH is not yet established.
- Long-term antithrombotic therapy is required for longer than 6 months following neurovascular stenting treatment.

The literature is observational and mainly case series based, and there is no long-term data regarding efficacy and safety. The role of neurovascular stenting in IIH to preserve rapidly deteriorating vision is not yet established, as there is a lack of quality data in this area. It may be useful for highly selected patients with IIH with venous sinus stenosis with an elevated pressure gradient and elevated ICP in whom traditional therapies have not worked.

And the following:

> The literature detailing stenting typically does not clearly separate the cohorts of IIH into those with visual loss, those with headaches alone and those with both. They typically also do not separate those with acute IIH, those with chronic IIH and those with IIH in ocular remission. Another major limitation is that case series are non-randomised; typically, they do not detail morphological stenosis type; they tend to be small in size with selection bias, and there is a lack of long-term follow-up.
>
> - Neurovascular stenting is not currently a treatment for headache in IIH.

The European Headache Federation (Hoffmann, 2018) has issued the following guidance on IIH:

> Venography brain imaging in IIH frequently demonstrates venous sinus stenosis. These stenoses typically regress after CSF drainage which induces reduction of ICP, consequently the stenoses are thought to represent an effect of raised ICP not the underlying cause. The extent of the stenoses does not correlate with ICP or predict the risk of visual loss. Some centres are conducting venous sinus stenting to treat IIH but utility is debated. Case series have reported improvement in symptoms of intracranial hypertension, however case selection is not randomised which can lead to selection bias and there are a lack of long term outcomes. Complications of the procedure are reported and include a short-lived ipsilateral headache in many, stent-adjacent stenosis that requires retreatment in a third, and in rare cases vessel perforation leading to acute subdural haematoma, stent migration, thrombosis and death. The comparative efficacy of stenting and shunting is not established, nor are the long-term efficacy, revision rate and safety data. There may be a role in some highly selected IIH patients.
>
> We do not advocate CSF diversion or shunting techniques to treat isolated headache symptoms due to the poor outcomes (ongoing headache in 68% at 6 months, 77% at 12 months and 79% at 2 years post-shunting), high revision rates and risk of complications. There is insufficient evidence to support venous stenting to exclusively treat headache.

The reviewed evidence suggests that stenting appears to be generally safe and results in an improvement of symptoms in a selected group of individuals with refractory IIH. The procedure should also be weighed against concerns for the development of in-stent and stent-adjacent stenosis and the implications those have on complications, symptom resolution, and subsequent procedures. The mechanisms that result in those outcomes are unclear. There is also a concern for serious complications, though rare, which pose a significant risk. While participant selection, stent mechanisms as well as type and duration of anticoagulant therapy have varied across studies, and standardized protocols for implementing venous sinus stenting also vary across institutions, stenting in select individuals with refractory IIH is considered in accordance with generally accepted standards of medical practice. Important considerations for treatment eligibility also include documentation of bilateral venous sinus stenosis, or unilateral stenosis and contralateral hypoplasia in conjunction with hallmark signs and symptoms of IIH, including the presence of papilledema, visual symptoms (for example, transient obscurations and photopsisas, vision loss, or diplopia) and elevated cerebrospinal fluid pressure on lumbar puncture.

Pulsatile tinnitus due to causes other than IIH (for example, arteriovenous malformation (AVM) or dural arteriovenous fistula)

The National Institute on Deafness and Other Communication Disorders (NIDCD), defines pulsatile tinnitus (PT) as a pulsing or whooshing sound in the ear synchronized with the individuals heartbeat. Malformations in blood vessels in the head or neck, especially if they are in or close to the ear, may alter blood flow resulting in tinnitus. PT may also be caused by brain tumors or abnormalities in brain structure. There is no randomized data supporting venous sinus stenting for the treatment of PT at present.

Pastalides and colleagues (2020) published a prospective single center clinical trial (NCT02734576) of 42 individuals with lateral venous sinus stenosis and severe or moderate PT. PT severity was graded according to the tinnitus handicap inventory (THI). The THI has a score from 0-100 based on answers from 25 standardized questions, a higher score indicates worst impact of tinnitus in daily living. The THI tool was used for assessment prior to treatment and at 1, 3, 6, and 12-months, and annual follow-up. A minimum score of 38 (consistent with moderate severity) was required for treatment. Individuals were also screened with contrast-enhanced MRA and contrast-enhanced MRV scans, those with clinical findings consistent with PT from venous origin, and imaging of at least 50% ipsilateral lateral venous sinus stenosis were included in the trial. Individuals with other causes of PT or a history of IIH were excluded. The results demonstrated the median THI score post-treatment was zero (average 1, range 0-38). There was complete resolution of PT in 39/42 individuals (THI score 0) and near-complete resolution in 2/42 individuals (THI scores 4 and 6) immediately post procedure. In 1individual, the PT improved after venous sinus stenting (THI score decreased from 52 to 38) but remained significant. This individual also had a jugular bulb diverticulum (JBD) that was not treated at the time of the venous sinus stenting and had a separate procedure to treat JBD which lead to near-complete resolution of the PT (THI score = 4). There were no serious adverse events. Follow-up with contrast enhanced MRV was available for 16/42 individuals. There was no evidence of in-stent stenosis, stent thrombosis or new adjacent stent stenosis. The saccular venous aneurysms treated with coils remained obliterated. During the follow-up period, there were no recurrences or worsening of PT reported. The median clinical follow-up was 5 months. The authors concluded that in carefully selected individuals, stenting may offer a resolution of PT caused by lateral sinus stenosis, however, proper clinical and imaging evaluation is needed as treatment effectiveness depends on a correct diagnosis. Study limitations includes the small sample size, lack of control group, less than half of those treated had follow up MRV imaging available, and the short follow-up period. Additionally, in the 2 individuals treated for lateral sinus stenosis and JBD at the same time, it could not be determined how much each condition contributed to the PT. Both conditions could independently cause PT, by treating both conditions at the same time the authors could not quantify how much each lesion contributed to the tinnitus.

Fiani and colleagues (2021), completed a literature review of studies that evaluated pulsatile tinnitus following venous stenting from 2001-2020 (16 studies, n=240). Most studies were small cohorts, particularly in the case of AVM which were single case studies. The authors concluded that although the data is promising, there are limitations to the findings and that the current literature does not provide sufficient data specifically investigating the correlation between stenting in venous sinus thrombosis and pulsatile tinnitus severity or resolution. Additional studies with larger cohorts and improved methodologies are needed to assess venous sinus stenting in individuals

with pulsatile tinnitus as a chief complaint when an underlying vascular disorder is identified (for example, arteriovenous malformation or dural arteriovenous fistula) and IIH is excluded as a diagnosis; at this time the use of venous sinus angioplasty and/or stenting is not considered in accordance with generally accepted standards of medical practice.

Nutcracker syndrome

Nutcracker syndrome is caused by arterial compression of the left renal vein between the superior mesenteric artery and the aorta (Hartung, 2005). Small case series and retrospective analysis (Chen, 2011; Hartung, 2005; Quevodo, 2014; Wang, 2012) report that endovascular stenting results in increased size of the left renal vein and improved peak velocity flow with improvements in flank pain, hematuria and proteinuria. Both Chen and Wang reported long-term follow-up for individuals at a median of 66 and 36 months, respectively.

Chen and colleagues (2011) retrospectively evaluated the endovascular stenting of 61 individuals with nutcracker syndrome and a median age of 26 years. Symptoms were hematuria, proteinuria or flank pain. Follow-up was completed by clinical exams and duplex ultrasound at 3, 6 and 12 months. Peak velocity in the aortomesenteric portion, and the anteroposterior diameter ratio of the renal hilum and the aortomesenteric portion of the left renal vein on duplex ultrasound after stenting was significantly decreased compared to that on duplex ultrasound before stenting. Peak velocity in the hilar portion did not statistically differ. Symptoms resolved or improved in 15, 24 and 20 of the 61 individuals within 1 week, and 1 and 6 months, respectively, after endovascular stenting. Symptoms remained unchanged in 2 cases and recurred in 1 case. A perioperative complication was noted in 1 individual, consisting of a stent mistakenly moved and poorly deployed in a left renal vein collateral, requiring operative intervention. Postoperative complications included stent migration into the right atrium, stent protrusion into the inferior vena cava and stent migration into the hilar left renal vein in 1 case each. Study limitations included the retrospective nature of the review. The authors concluded that based on their long-term follow-up, endovascular stenting is a safe, effective procedure in select adults with persistent, severe symptoms that are unresponsive to conservative therapy at 24 months of follow-up.

Wang and colleagues (2012) assessed 30 individuals diagnosed with nutcracker syndrome admitted for endovascular treatment from January 2004 to August 2010. Each individual received one self-expanding metallic stent in the compressed portion of the left renal vein during the operation, and 3 with severe left-sided varicoceles received left gonadal vein embolization. The postoperative follow-up was 12 to 80 months. No perioperative complications occurred. Postoperatively, 2 cases of stent migration were found at 12 months. At 1-month follow-up, subjects individuals, including 2 who had persistent but less microscopic hematuria than before treatment. The clinical symptoms of nutcracker syndrome almost disappeared at 3 months after the treatment. All stents were patent at the duplex scan examination, without restenosis, and no secondary recurrence of the symptoms occurred at the end of the follow-up. Study limitations included the retrospective nature of the review. The authors concluded that endovascular treatment is a safe, effective, and minimally invasive technique that provides good long-term patency rates for nutcracker syndrome. Additionally, the authors stated, “further experience and follow-up are needed before accepting such a procedure for the superior choice of the treatment for nutcracker syndrome.”

Avgerinos and colleagues (2019) published the results of a single center retrospective cohort study of 18 individuals with nutcracker syndrome treated with left renal vein (LRV) stenting. The stents were deployed then dilated with confirmation of landing and lack of residual stenosis assessed by intravascular ultrasound (IVUS). Follow up occurred at 1, 3, 6, and 12 months with clinical evaluations and ultrasounds to assess LRV patency. The resolution of symptoms occurred on an average of 41±26.6 months with 9 individuals achieving complete resolution and 4 with partial resolution. Of the individuals with residual symptoms, 3 previously underwent LRV transposition surgery, and 2 required renal auto-transplantation surgery despite patent stents. Stent re-intervention was required in 3 individuals at 5.8, 16.8, and 51.6 months due to recurrence of symptoms or stent restenosis. The authors concluded larger studies with longer follow-up are needed. Renal vein stenting appears to have low risk; however, further study is warranted to determine the ideal candidate for successful LRV stenting that will result in resolution of symptoms.

Existing evidence from small case series and retrospective studies is insufficient to support the use of venous angioplasty as a generally accepted treatment for nutcracker syndrome. Additional long term and comparative studies against left renal vein transposition are needed.

Thrombosed Filter Bearing Inferior Vena Cava

Use of venous angioplasty, with or without stenting has been proposed in the setting of incomplete thrombus resolution of a filter-bearing inferior vena cava, particularly if filter retrieval is not possible. The method may involve “balloon maceration” of the thrombus or filter-bearing IVC, or placing a stent inside the IVC, thereby crushing the existing IVC filter. At this time there is limited data available regarding both short- and long-term outcomes, including patency rates and other complications, and further investigation is needed (Golarz, 2010; Neglén, 2011). The current published experience of IVC thrombosis management in relation to filters is either anecdotal or limited to a small group of individuals (Sildiroglu, 2012).

Definitions

Budd-Chiari syndrome: A rare disease characterized by obstruction of outflow from the small hepatic veins to the level of termination of the inferior vena cava.

Idiopathic intracranial hypertension: Occurs when intracranial pressure increases without a reason. Also known as pseudotumor cerebri or benign intracranial hypertension.

Iliac vein compression syndrome (IVCS): IVCS occurs when compression of the iliocaval venous territory is severe enough to inhibit the rate of venous outflow. A definitive diagnosis of IVCS requires demonstration of a stenotic or occlusive venous lesion on vascular imaging and high suspicion that the lesion is the cause of clinical features consistent with venous compression (for example, DVT or history of a DVT, extensive lower extremity swelling, predominance of venous claudication, or stigmata of chronic venous disease such as skin changes or ulceration).

May-Thurner syndrome: A rarely diagnosed iliac vein compression syndrome defined as extrinsic venous compression by the arterial system against bony structures in the iliocaval venous territory, most commonly of the left common iliac vein by the right common iliac artery, which increases the risk of deep vein thrombosis.

Nutcracker syndrome: A rare condition caused by arterial compression of the left renal vein between the superior mesenteric artery and the aorta.

Superior vena cava syndrome: A group of symptoms that occur (often as a result of cancer) when the superior vena cava is blocked (occlusion or vein narrowing [stenosis]). The most common symptoms are coughing, trouble breathing, and swelling in the face, neck, upper body or arms.

Tinnitus: Is the subjective perception of sound that does not have an external source. The phantom sound may be experienced as a ring, buzz, roar, whistle, hum, click, hiss, or squeal. The sound may unilateral or bilateral, soft or loud, low or high pitched, transient or continuous. In rare cases, the sound pulsates rhythmically, with an individual's heartbeat, this is known as pulsatile tinnitus.

Venogram: An X-ray test that takes pictures of blood flow through the veins in a certain area of the body.

Venous thoracic outlet syndrome (vTOS): A rare disorder caused by compression of peripheral nerves and vascular structures along their course through the upper thoracic aperture to the axilla.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, Definitions, References, and Websites sections.
Revised	02/16/2023	MPTAC review. Added new MN criterion for IIH. Updated Discussion, Coding and References sections**.**
Reviewed	02/17/2022	MPTAC review. Updated Discussion/General Information, References, and Website sections.
Revised	11/11/2021	MPTAC review. Corrected typo in INV and NMN section. Updated References and Website sections.
Reviewed	11/05/2020	MPTAC review. Updated Discussion/General Information, References and Website sections. Reformatted Coding section.
New	11/07/2019	MPTAC review. Initial document development. Moved content of SURG.00122 to new clinical utilization management guideline document with the same title.