



Management of Obstruction of the Femoroiliocaval Venous System

Introduction:

The ACP Guidelines Committee was developed to assess medical literature and make recommendations to help physicians make evidence-based decisions for the benefit of patients with venous disorders. The Committee's goals are to create documents reviewing specific medical conditions, and then, using expert opinion, to make recommendations for or against certain methods of evaluation and treatment.

Process for this document:

The recommendations in this document are based on a literature review by a working group of the ACP Guidelines Committee. The document was then drafted by the workgroup chair, and the full Guidelines Committee reviewed the document. A conference call was held and the document and the workgroup's recommendations discussed. Edits to the document were then proposed. The location of publication of the document was also discussed and voted upon. In this case, the Committee voted to publish the literature review and its recommendations online on the ACP website. The edited version of the document was then shared with the Committee and each member was asked to vote whether to endorse the edited draft along with its recommendations using an online anonymous survey. A 75% majority was required for approval. The documents were approved by the Guidelines Committee.

Method of recommendation:

The grade of recommendation for or against a specific diagnostic or therapeutic intervention may be strong (1) or weak (2), based upon the risk:benefit ratio. The quality of evidence may be rated as high (A), medium (B), or low (C).

Recommendations for Management Of Obstruction of the Femoroiliocaval Venous System

1. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic iliac and common femoral venous obstructions in patients with lower extremity pain or edema affecting QOL not palliated by compression and for patients with impending or active lower extremity venous leg ulceration. Grade 1B
2. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic IVC obstructions in patients with lower extremity pain or edema affecting QOL not palliated by compression and for patients with impending or active lower extremity venous leg ulceration. Grade 1C
3. We recommend venous balloon angioplasty and stenting as an adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis in order to maintain vein patency and flow when a residual stenosis is found on post thrombolysis imaging. Grade 1B

4. We recommend venous balloon angioplasty and stenting for treatment of non-thrombotic and post-thrombotic iliac venous obstructions in patients with chronic pelvic pain, deep dyspareunia, or low back pain which severely affect the QOL when other likely causes have been excluded and the severity of the iliac vein obstruction is considered sufficient to explain the symptoms. Grade 1C

These recommendations do not address other generally accepted uses of venous BA/stenting such as for dialysis access outflow obstructions, superior vena cava syndrome, Budd-Chiari syndrome, or stenosis associated with central venous catheters or transvenous pacemaker leads.

Clinical diagnosis, imaging, and patient selection are beyond the scope of these recommendations, though they are addressed in many of the references and will be addressed further in future reviews.

Non-thrombotic and Post-thrombotic Venous Obstruction

A. Topic Summary:

Obstructions of the femoroiliacaval veins (FICV) cause chronic venous hypertension and high venous pressures in the tissues peripheral to the site of obstruction, which can result in inflammatory changes that can be a major cause of physical disability and chronic pain. The common clinical manifestations of chronic venous hypertension include pain in the lower extremities (LE), vulva, pelvis, or low back at rest, with standing or walking, and occasionally pain with intercourse. Lower extremity edema and/or lymphedema secondary to venous obstruction and venous hypertension may reduce physical activity due to the heaviness or stiffness of the lower extremities. In addition, FICV obstruction predisposes patients to recurring cellulitis of the lower extremity. Long-standing venous hypertension can lead to inflammatory skin changes including stasis dermatitis, which may progress to venous leg ulceration (VLU).

When these symptoms limit physical activity and enjoyment, important to consider venous obstruction as a treatable cause.

The Post-Thrombotic Syndrome (PTS) is the long-term sequela of unresolved deep venous thrombosis of the abdominal, pelvic, or leg veins resulting in chronic pain, swelling, and skin changes occurring in approximately 20-50% of patients treated with anticoagulation. Residual venous obstruction from incomplete recanalization after deep vein thrombosis (DVT) in the FICV places the patient at a much higher risk of recurrent DVT.

Medical management of FICV obstruction includes elevation, compression with elastic or inelastic devices, compression pumps, and analgesics. Anticoagulation is an adjunct to reduce the risk of rethrombosis in selected patients, but does nothing to correct the chronic venous hypertension and resulting long-term tissue damage.

There is robust clinical evidence in the peer-reviewed medical literature that alleviating venous obstruction utilizing balloon angioplasty and stenting is feasible in the vast majority of patients with good to excellent results in terms of stent patency, relief of symptoms, and recurrent stenosis. The evolution of balloon angioplasty and stenting of the FICV obstructions over the past 20 years has established it as the technique of choice for most severely symptomatic patients. Since maintaining venous patency is the ultimate goal, hybrid techniques combining balloon angioplasty (BA) and stenting with open surgical endophlebectomy have been described for improving venous inflow into the stented vein segments. However, open surgical treatment such as femoro-femoral or femoro-caval bypass, which once were the only options for these patients, now are viewed as procedures of last resort when BA/stenting is not feasible or has failed.¹ Because clinical success rates are high and complications are uncommon, BA/stenting has greatly improved the

QOL of many patients who previously suffered the long-term consequences of untreated chronic venous obstruction in the FICV.

B. Literature Review:

In 1999, Blattler and Blattler reported a series of 12 patients treated with stents for post-thrombotic iliac vein obstruction associated with venous claudication, neurogenic claudication, or pelvic and low back neuralgias due to collateral venous congestion at the cauda equina or spinal cord.² In 1998, Mickler, et al, reported thrombectomy and stent implantation for left iliac vein thrombosis associated with a venous spur due to iliac vein compression.³ In 2000, Neglen, et al, reported stenting of the iliac veins for chronic primary and post-thrombotic obstruction.⁴

Raju reviewed management options for chronic iliac vein stenosis and occlusion that he presented in 2011 at the Society of Vascular Surgery Annual Meeting and published in 2013. He documented the results of approximately 1500 patients treated with BA/stenting collected from previous peer-reviewed publications. Raju assigned a Grade 1B recommendation for iliac vein stenting for patients with disabling symptoms in whom conservative therapy had failed. He assigned a Grade 2B recommendation for patients with less severe symptoms. Raju reported stent patency of 90-100% for non-thrombotic obstruction and 74-89% for post-thrombotic obstruction at 3 to 5 years post-treatment. He reported clinical relief of pain at 86-94%, relief from LE swelling at 66-89%, and VLU healing at 58-89%. Procedural success in recanalization of chronic total occlusions was 83-95%. Raju reported no deaths or pulmonary embolism and access site complications were reported in less than 1% of patients. Stent-related complications or bleeding requiring transfusion were rare.⁵

Since Raju's review, several notable studies report outcomes related to stent patency, symptom relief, venous leg ulcer (VLU) healing and re-intervention rates. Primary stent patency rates range from 38%

to 100% and secondary patency rates range from 79% to 100% in the studies listed below. Symptom improvement was shown in 81% to 95.2% of patients with follow-up as long as 36 months. Improvement in quality of life measures including the SF-36 questionnaire and Visual Analog Scale pain scores was seen in several studies. VLU healing was noted in 61% to 80% of patients.

Neglen, et al, reported patency rates following stenting of chronic FICV obstruction in 708 patients including 25 treated for an obstructed inferior vena cava (IVC) filter. He reported no difference in patency between the IVC obstruction group and the iliofemoral vein obstruction group at 54 months follow-up. Primary and secondary patency rates were 38% and 79% (filter present), 40% and 86% (no filter), 42% and 84% (stenting peripheral to a filter), 32% and 86% (stenting across a filter).⁶ Titus, et al, reported stenting of chronic obstruction in forty iliac vein limbs with one-year primary patency of 78.3% and secondary patency of 95% with symptomatic improvement in 83%.⁷ Osse and Thorpe reported stenting 46 patients including 9 with total IVC occlusions with primary patency in the successfully recanalized patients of 70% and a secondary patency of 98% with follow-up of 6 months to 15 years, mean 5.8 years.⁸ Ye, et al, reported four year follow-up of iliac vein stents placed for non-thrombotic lesions with a 98% primary stent patency.⁹

Endophlebectomy of the common femoral vein can be performed as an adjunct to iliac vein stenting to increase inflow into the stented vein segment and was reported by deWolf, et al, in 19 cases with primary patency of 77% during a follow-up of 2-20 months, mean 7.9 months.¹⁰ deWolf, et al, also reported 75 BA/stenting procedures for chronic iliofemoral obstruction in 63 patients. Eighty-six percent of the patients reported a history of LE DVT and 56% were found to have a May-Thurner arterial compression of the iliac vein. Primary patency was 74%, assisted primary patency was 81%, and secondary patency

was 96% at one year. Secondary procedures to achieve assisted primary patency or secondary patency included re-stenting, catheter-directed thrombolysis, endophlebectomy of the common femoral vein, and construction of an arterio-venous fistula. Symptoms were relieved or significantly improved in 81% of patients.¹¹

Hager, et al, reported stenting 77 iliac vein limbs in 70 patients for iliac vein compression, most of which were post-thrombotic. Complete or partial symptom relief was reported in 92.9% of the post-thrombotic patients and in 95.2% of the non-thrombotic patients. Overall primary patency at 36 months was 91% with secondary patency of 95%. One patient required transfusion of one unit of blood.¹²

Raju and Ward reported on 107 iliac limbs treated with BA/stenting for chronic FICV obstruction in 95 patients aged 80 to 96 years, median 83 years. Patients were selected for treatment if they failed to respond to compression or if compression was difficult or impossible to achieve. Primary and assisted primary patency at 5 years were 52 and 90%, respectively. Pain completely resolved in 43% and the pain score significantly improved in 71%. LE swelling resolved completely in 25% and improved significantly in 63%. Seventy percent who experienced prior LE cellulitis had no recurrence and 61% of active VLUs healed. There was no mortality and there were few minor complications. Raju concluded that iliac vein stenting "appears to offer a safe and effective option in octogenarians and nonagenarians when compression fails, is difficult, or is impossible".¹³

Rossi, et al, presented at the American Venous Forum in February, 2015 a randomized, double-blinded study comparing clinical versus endovascular treatment of ilio caval obstruction with BA/stenting. They studied 40 patients with 50 highly symptomatic iliac vein obstructions. All lesions were successfully treated. Pain scores on a visual-analog scale

declined from a median of 8.5 to 1.8 following stenting and from 7.5 to 7.0 after clinical treatment with compression and venoactive drugs or warfarin. The rate of ulcer healing was 80% in the stented group and 33.3% in the clinical treatment group at 6 months. The SF-36 Quality of Life Questionnaire score improved from a median of 53.9 to 85.0 in the stented group and from 48.3 to 59.8 in the clinical treatment group. Primary and assisted patency rates were 96% and 100%, respectively.¹⁴

Fremed, et al, reported a retrospective review of 107 patients who underwent ilio caval stenting for chronic obstruction and found that 11 patients required reintervention for recurrent symptoms. The average interval to reintervention was 5.5 months. Six of the 11 patients were found to have iliofemoral stenosis distal to the previously placed stents, 5 had in-stent restenosis, and 3 had malposition of the stent. Secondary procedures included a new stent placement in 9, balloon angioplasty alone in 2, and catheter-directed thrombolysis in 1.¹⁵

Raju, et al, reported a series of 39 patients treated over 13 years for iliac vein stenosis who also had post-thrombotic femoral vein occlusions. Seven of the patients were treated also for saphenous vein reflux. Cumulative improvement in the visual analog pain score (0-10) was 3 or more in 87% of the patients at 2 years. Seven of 22 limbs with grade 3 limb swelling improved at least 1 grade after stenting and the other 15 reported subjective improvement in limb swelling. Four of 7 active VLUs healed during follow-up.¹⁶

Yin, et al, reported iliac vein stenting for arterial compression (May-Thurner) who also had significant insufficiency of the great saphenous vein. They treated 121 patients with iliac vein stenting and ipsilateral endovenous LASER ablation (EVLA) and 86 patients with EVLA of the saphenous vein alone. Technical success with stenting was 100% and the 4-year primary patency was 93.3%. Median follow-up was 70 months. LE pain, edema, and QOL scores

improved significantly in the stent+EVLA group but not in the EVLA-alone group. This strongly supports the observations by others that treating the venous outflow obstruction is an important component of treating these patients with mixed iliac vein obstruction and saphenous vein reflux.¹⁷

Erben, et al, reported in February, 2015 at the American Venous Forum a series of 66 patients treated for chronic, nonmalignant IVC occlusion treated over a 13 year period. Most had previous DVT with or without pulmonary embolism, but 6 had previous iatrogenic injury or congenital hypoplasia. All underwent angioplasty and stenting of the IVC and one or both iliac limbs. Complications included 1 IVC hematoma, 1 groin hematoma, and 1 femoral vein thrombosis. Primary patency, assisted primary patency, and secondary patency at 36 months were 80%, 88%, and 91%. Symptoms completely or partially resolved in 83%.¹⁸

Chronic pelvic pain caused by venous reflux in the absence of other etiologies, described as pelvic congestion syndrome (PCS) and associated with dyspareunia, post-coital pain, and low back pain, has been treated for the past 20 years with left ovarian and, sometimes internal iliac vein, embolization. Meso-aortic compression of the left renal vein and iliac vein compression (May-Thurner) have been reported occasionally to cause pelvic congestion symptoms, but these are being recognized more frequently as clinical awareness and imaging techniques improve. Hartung reported in 2012 at the European Venous Forum treating a series of patients with PCS with iliac vein stents for arterial compression in 59 patients and for post-thrombotic obstruction in 10 patients. Primary and assisted patency rates at 5 and 10 years were 95% and 100%, respectively. Pelvic pain scores (chronic pelvic pain + dyspareunia) decreased from a median of 10/20 preoperatively to a median of 1.9/20 at last follow-up (median 32 months, range 1-150 months).¹⁹ Daugherty and Gillespie subsequently

reviewed 19 patients with non-thrombotic ilio-caval obstruction treated with BA/stenting for PCS. Fifteen of 19 patients experienced complete resolution of pelvic pain and 14 of the 17 sexually active patients experienced complete resolution of their dyspareunia. Of the 15 who experienced LE pain or edema, 13 reported complete resolution at last follow-up.²⁰ Daugherty reported at the American Venous Forum in 2015 an expanded retrospective review of 33 patients treated with iliac vein stenting for severe PCS due to arterial compression. Follow-up for 26 patients was 1 to 83 months, mean 18. On an analog scale of 0-10, the median scores for pelvic pain improved from 8 to 2, dyspareunia improved from 8 to 2, post-coital pain improved from 8 to 0, low back pain improved from 5 to 2, left lower extremity pain improved from 5 to 2, and right lower extremity pain improved from 4 to 2. None of the patients reported recurring pelvic symptoms during follow-up. Primary patency was 100%.²¹

Venous Obstruction Uncovered After Thrombolysis:

A. Topic Summary:

Acute thrombosis of the LE veins may be limited to the LE, may involve the iliac veins and, sometimes, the IVC. Eighty percent of iliofemoral DVTs, DVTs that involve the ilio-caval segment in addition to the veins below the inguinal ligament, have an underlying iliac vein compression. This compression is thought to be a lesion which increases the risk of iliofemoral DVT, especially in individuals who have other risks for thrombosis including oral contraceptive use.²² For more than 20 years, catheter-directed thrombolysis has been utilized to reduce the burden of obstructive acute thrombus in the iliofemoral veins. Resolution of the thrombus relieves pain and swelling in the LE which may be very important clinically in some patients, but resolution of large vein thrombus also is thought to reduce valve damage and to reduce the likelihood of future post-thrombotic-syndrome.

B. Literature Review:

Semba and Dake reported treatment of acute iliofemoral DVT with catheter-directed thrombolysis in 1994.²³ In 1999, Mewissen, et al, reported a 473 patient multicenter registry of patients who underwent catheter-directed thrombolysis (CDT). The patients who also were treated with venous stents had a 73% 1-year patency while those who did not receive a stent had a 54% 1-year patency.²⁴ Comerota, et al, reported 68 patients treated for acute iliofemoral DVT with CDT and stenting who were compared with 30 retrospectively-matched patients who were treated with anticoagulation alone. The CDT/stent patients had fewer LE symptoms ($p=0.006$), better physical functioning ($p=0.046$), fewer stigmata of chronic venous insufficiency ($p=0.033$), and less health distress ($p=0.022$) with a mean follow-up of 16 months.²⁵

AbuRahma, et al, reported in 2001 a retrospective study in which 51 patients with acute iliofemoral DVT were allowed to choose CDT (including BA/stent) and anticoagulation or anticoagulation alone. At 6 months, the CDT+BA/stent patients were found to have 83% venous patency rates while the anticoagulation alone group had 24% patency. At 5 years, 78% of the CDT+BA/stent group was symptom free compared to 30% of the anticoagulation alone group.²⁶

Three randomized clinical trials have been reported utilizing CDT with venous BA/stenting to treat extensive iliofemoral DVT with a goal of preventing PTS and its complications. All three groups were compared to randomized anticoagulation only control groups.^{27,28,29,30}

The TORPEDO trial randomized 189 patients with acute proximal DVT to groups treated with CDT/BA/stenting versus anticoagulation alone. The incidence of PTS at 2.5 years of follow-up was 6.8% in the CDT/BA/stent arm and 29.6% in the anticoagulation alone control. The rate of recurrent venous

thromboembolism was 4.5% in the CDT/BA/stent group and 16% in the anticoagulation alone group.

The CaVenT multicenter randomized trial included 209 patients with femoral and/or iliac DVT. The incidence of PTS at follow-up was 41.1% in the CDT/BA/stent group and 56.6% in the anticoagulation alone group. Only 15 of the 101 patients treated with catheter-directed (CDT) thrombolysis were stented while many observers might have expected a stent rate of 80%, possibly a reason that the difference between CDT treatment and medical treatment is not greater than observed. Two-year vein patency was 83.7% in the CDT/BA/Stent group compared to 65% in the anticoagulation alone group. Scores on the validated Villalta PTS scale were better in the stented group (3.53 vs 4.65, $p=0.046$).

Venous angioplasty for residual stenosis from extrinsic compression or from phlebosclerotic changes which are apparent after CDT is viewed as an essential adjunct in treating these patients since a residual stenosis places the patient at higher risk for rethrombosis. The ATTRACT trial recently completed enrollment and may add to the understanding of the utility of pharmacomechanical thrombolysis and catheter-directed thrombolysis for acute iliofemoral venous thrombosis.

Guidelines of Other Societies

In 2009, the American Venous Forum published the most comprehensive book of guidelines for treatment of venous disorders written to date which includes extensive scholarly review and references supporting the guidelines. Guideline 4.17.0 gives a Grade 1 recommendation (we recommend) for endovenous stenting to improve symptoms and QOL for patients with chronic iliofemoral obstruction and the Grade of evidence is rated A (high quality). Guideline 4.18.0 gives a Grade 2 recommendation (we suggest) for endovascular stenting for reconstruction of complex ilio caval

venous occlusions and the Grade of evidence is rated B (moderate quality).^{31,32}

O'Donnell, et al., published in 2014 clinical practice guidelines of the Society of Vascular Surgery and the American Venous Forum for management of venous leg ulcers. This extensive review recommends BA/stenting of obstructed iliofemoral venous outflow in patients with VLU.³³

In addition to the guidelines referenced earlier from the American Venous Forum and the Society for Vascular Surgery (references 5, 6, and 14), a number of other society guidelines exist which also

support the use of BA and stenting for symptomatic venous obstructions:

2006-Society of Interventional Radiology Quality Improvement Guidelines³⁴

2006-Society of Interventional Radiology Position Statement³⁵

2011-American Heart Association Scientific Statement³⁶

2012-Society for Vascular Surgery and American Venous Forum³⁷

2014-American Heart Association Scientific Statement³⁸

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The American College of Phlebology guidelines are based on consensus documents and research. These consensus documents, as well as other materials reviewed in forming the ACP guidelines included but were not limited to:

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Disclaimer

Adherence to these guidelines will not ensure successful performance. Furthermore, these guidelines should not be deemed inclusive of all proper methods of treatment or exclusive of other protocols reasonably directed to obtain the same results. The physician and patient must make the ultimate judgment regarding the propriety of any performance and interpretation of studies in light of all the circumstances presented by the individual patient.

These guidelines reflect the best available data at the time it was prepared; the results of future research or technology may require alteration of the minimum standards and reporting as set forth in this guideline.