



Iliac Vein Stent Placement and the Iliocaval Confluence

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Objective: Prior literature has recommended routine iliac vein stent extension into the inferior vena cava (IVC) to assure adequate outflow for iliac vein stenting procedures. Our bias was that only the lesion should be stented without routine stent extension up to the IVC. We report our experience with this limited stenting technique.

Methods: From 2012 to 2015, 844 patients (1,216 limbs) underwent iliac vein stenting for non-thrombotic iliac vein lesions (NIVLs). All limbs were evaluated in accordance with the presenting sign of the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) score, and duplex scans and intravascular ultrasound (IVUS) showing more than 50% cross-sectional area or diameter reduction. All study patients had failed 3 months of conservative management. The procedures of iliac vein stenting were all office based. Two techniques were compared: (1) placement of the iliac vein stent to cover the lesion and terminating cephalad into the IVC if the lesion involved the common iliac vein and (2) placement of the iliac vein stent to cover the lesion only and not passing the iliocaval confluence if the lesion only involved the external iliac vein. Complications were assessed during 30-day follow-up using the duplex scan technique to look for thrombosis.

Results: Of the total 844 patients, 543 (64%) were women. The average age was 66 (± 14.2) years (range, 21–99 years). The stent was placed in the left lower limb in 474 patients and bilaterally in 370 patients. The presenting sign in accordance with the CEAP classification was C3 = 626, C4 = 404, C5 = 44, and C6 = 141. The average iliac vein stenosis by IVUS was 62% ($\pm 12\%$ standard deviation [SD]). We had 715 patients with the iliac vein stent extending into the IVC, and of these, 8 patients had thrombosis within 30 days after the procedure. On the other hand, 501 patients had the iliac vein stent without crossing the iliocaval confluence, and of these, 4 patients had thrombosis within 30 days of the procedure. There was no difference between these 2 groups in regard to gender ($P = 0.1$) or age ($P = 0.3$). Laterality was statistically different ($P < 0.0001$) with more stents to be extended into the IVC if the lesion is in the left lower limb. Comparing these 2 groups in regard to 30-day thrombosis as a complication was not statistically significant ($P = 0.6$). There was no statistical difference between the 2 groups in regard to the presenting sign CEAP ($P = 0.6$).

Conclusions: These results question the need for routine iliac vein stent extension into the IVC in patients with NIVLs. We were not able to demonstrate a significant risk of thrombosis with just placing the stent to cover the lesion only with short-term follow-up.

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INTRODUCTION

Percutaneous stenting of the ilio caval venous outflow is a minimally invasive intervention that has proven effective and safe in the management of chronic venous insufficiency (CVI).¹ This procedure has been performed with low morbidity, long-term stent patency, a low rate of in-stent stenosis, and limited need for reintervention. It has resulted in sustained relief of limb symptoms, a high rate of healing of venous leg ulcers, and improvement of patient's quality of life.²⁻⁴

A recent randomized double-blinded study by Rossi et al.⁵ comparing medical treatment versus iliac vein stenting in chronic venous insufficiency has concluded that iliac vein stenting is safe and promotes effective relief of symptoms and improvement in the quality of life compared with medical treatment alone in symptomatic patients with CVI. Despite the prevalent implementation of iliac vein stenting procedure in treating patients with CVI, we are still lacking guidelines, and the optimal method of performing this procedure remains to be explored.

Neglén and Raju have recommended an extension of the stent into the inferior vena cava (IVC) when treating a focal obstruction adjacent to the confluence of the common iliac vein to avoid caudal migration and early recurrence of the stenosis. With this approach of stent extension, it may add more time to the procedure or may require insertion of 2 or more stents to achieve proper insertion of the stent into the IVC.^{6,7} Our bias was that only the lesion be stented without routine stent extension into the IVC. We report our experience with this focused stenting technique.

METHODS

We performed a retrospective study from 2012 to 2015 on 1,216 limbs of 844 patients with CVI who underwent iliac vein stent placement in an office-based practice (Total Vascular Care®) under local anesthesia without sedation. There were no inpatients in this data set. All iliac vein lesions were non-thrombotic. All of these patients had already failed to have improvement of their lower limb swelling with conservative management for 3 consecutive months that included compression therapy and leg elevation. The limbs were classified in accordance with the presenting sign of Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification defined by the American Venous Forum.⁸ The inclusion criterion was patients with CVI and a CEAP score of 3 and higher, and the exclusion criterion was patients with a CEAP score less than 3 and aged <40 years.

Evaluations of CVI were performed using history, physical examination, and venous duplex studies and intravascular ultrasound (IVUS) (iLab™, Boston Scientific) of the iliofemoral venous system. The measurement of stenosis was compared with adjacent nonstenotic segments. If more than 50% diameter or cross-sectional area reduction was noted, stent deployment was performed. Wallstent (Boston Scientific) was used in all procedures for nonthrombotic iliac vein stenosis, ranging 8–24 mm in diameter and 40–90 mm in length. Heparin flush was used in 95% of patients during the procedure. The stents were oversized by 15 to 20% to allow proper apposition.

All patients were then observed in the recovery room before discharge. Postoperatively, the patients were given clopidogrel (Plavix) 75 mg for 3 months or continued their existing anticoagulants.

All of the 1,216 iliac vein stenting procedures with venograms were reviewed to determine the iliac vein stent location and its correlation with the ilio caval confluence. Two techniques were compared: (1) placement of the iliac vein stent to cover the lesion and terminating cephalad into the IVC if the lesion involved the common iliac vein and (2) placement of the iliac vein stent to cover the lesion only and not passing the ilio caval confluence if the lesion only involved the external iliac vein. There was no specific length extension into the IVC, the stents were placed cephalad just beyond the ilio caval confluence. Complications were assessed during 30-day follow-up using the duplex scan technique to look for thrombosis.

Statistical analysis was performed using a chi-square and student's *t*-test. The protocol for the collection and interpretation of data conformed to the principles set by the Declaration of Helsinki. Approval from the Institutional Review Board of Total Vascular Care Incorporated (registered with the U.S. Office for Human Research Protections) was obtained, and consent was waived as the data are blinded and retrospective.

We analyzed the data by correlating the 2 groups with age, gender, laterality, and iliac vein thrombosis as a short-term complication to the stenting.

RESULTS

From February 2012, to July 2016, we performed a total of 1,216 iliac vein stenting in 844 patients with IVUS. Of the total patients, 543 (64%) were women. The average age of the patient population was 66 (± 14.2) years (range, 21–99 years). The stent was placed in the left lower limb in 474 patients and

Table I. Patient characteristics in both groups

| | Stent extended into the IVC | Stent not extended into the IVC |
|--------------------------|-----------------------------|---------------------------------|
| The average age in years | 65.7 | 66.6 |
| Men | 247 | 196 |
| Women | 468 | 305 |
| Right | 211 | 344 |
| Left | 504 | 157 |
| C3 | 386 | 240 |
| C4 | 226 | 178 |
| C5 | 24 | 20 |
| C6 | 79 | 63 |

bilaterally in 370 patients. None of the patients had a prior history of deep venous thrombosis. Patients were distributed based on the presenting sign of CEAP as follows: C3 = 626, C4 = 404, C5 = 44, and C6 = 141. The average iliac vein stenosis was 62% ($\pm 12\%$ standard deviation [SD]).

We had 715 procedures with the iliac vein stent extending well into the IVC, and of these, 8 cases (1.1%) had thrombosis within 30 days after the procedure. The average age was 65.7 (± 14.3) years. The number of women in this group was 468; the stent was placed in the left lower limb in 504 patients.

On the other hand, we had 501 procedures of iliac vein stenting without crossing the iliocaval confluence, and of these, 4 cases (0.8%) had thrombosis within 30 days of the procedure. The average age was 66.6 (± 14) years. The number of women in this group was 305; the stent was placed in the left lower limb in 157 patients.

There was no difference between these 2 groups in regard to gender ($P = 0.1$) or age ($P = 0.3$). Laterality was statistically different ($P < 0.0001$) with more stents to be extended into the IVC if the lesion is in the left lower limb. Comparing these 2 groups in regard to 30-day thrombosis as a complication was not statistically significant ($P = 0.6$). There was no statistical difference between the 2 groups in regard to the presenting sign CEAP ($P = 0.6$).

Table I demonstrates patient characteristics in both groups.

DISCUSSION

Although the procedure of iliac vein stenting is becoming one of the modalities to manage patients with documented iliocaval lesions, we do not have standard guidelines for the techniques of this procedure. Prior literature recommended an extension of the stent proximally into the IVC when stenting a

lesion adjacent to the confluence of the common iliac veins to prevent complications of missed proximal lesions and thrombosis.

Our theory suggests that stents need to cover only the lesion without the routine need for an extension of the stent all the way into the IVC. In our data set, we found that there was no difference in earlier results for thrombosis between our approach to stent the lesion only and the practice of extending it into the IVC. We believe that our approach may decrease the time and cost of the procedure by decreasing the need for additional stents as well as decrease the exposure to radiation. In a prior study, we found that the placement of >1 iliac vein stent resulted in higher cumulative air kerma and fluoroscopy time.⁹

In prior literature, the technique of iliac vein stenting has been investigated with different factors thought to play a role in the improvement of the outcome of the procedure and to decrease the complications related to it. However, it is not known which exact factors contribute to the success or to the development of complications, especially thrombosis, after specific venous stenting technique, or how the providers decide whether the stenting has resolved the existing venous pathology. Factors related to the patients themselves and to the technique of how the stent is placed should be part of future studies and should be taken into consideration when managing patients with CVI with iliac vein stenting. Other factors related to thrombosis and restenosis remain to be elucidated. This would encourage more work to look for the optimal technique of this procedure and more effort is needed to better understand the etiology and treatment using venous stenting for these lesions.^{10–12}

With the development and revolution of new venous-specific stents in the near future with higher radial force, longer length with provision for different shapes to allow proper stent-vein wall apposition, the risk of stent stenosis or occlusion may possibly decrease. This may lead us to enter a whole new era of iliac vein stenting.

Some limitations of our study included that it is of retrospective nature and patients were treated in a single center. The patients included in our study were nonthrombotic. The sample size of the patient population affected with stent thrombosis was small with limited follow-up.

CONCLUSIONS

These results question the need for routine iliac vein stent extension into the IVC. We were not able to

demonstrate a significant risk of thrombosis with just placing the stent to cover the lesion only with short-term follow-up.

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